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MEMORANDUM

Date: March 31, 2013

To: Dan Cartin, Director
OLLS

From: Anne McGihon
Peggy Toal
On behalf of the Acupuncture Association of Colorado

Cc: Leo Boyle

Re: Objections to OLLS Memorandum on Rule 211, State Board of Physical Therapy: ***Rules of the State Physical Therapy Board, Department of Regulatory Agencies, concerning physical therapists, 4 CCR 732-1 (LLS Docket No. 120310; SOS Tracking No. 2012-00318) ("Rule 211 Memo").***

Per your request, please find attached:

1. Our Summary of Objections to the Rule 211 Memo;
2. Our comments on the Rule 211 Memo, on an annotated copy of the actual memorandum;
3. Attachment 1, a blacklined Rule 211 marked to show changes from the 2007 version of the rule to the 2012 version;
4. Attachment 2, summary of articles on "mechanical stimulation;" and
5. Our Memorandum on Rule 211 forwarded by transmittal letter dated February 12, 2013.

MEMORANDUM

Date: March 31, 2013

To: Dan Cartin, Director
OLLS

From: Anne McGihon
Peggy Toal
On behalf of the Acupuncture Association of Colorado

Cc: Leo Boyle

Re: Summary of Objections to OLLS Memorandum on Rule 211, State Board of Physical Therapy:
Rules of the State Physical Therapy Board, Department of Regulatory Agencies, concerning physical therapists, 4 CCR 732-1
(LLS Docket No. 120310; SOS Tracking No. 2012-00318) ("Rule 211 Memo").

You requested an outline of our comments on the Rule 211 Memo. Our comments are generally categorized as follows:

(A) **1.** The definition of "physical therapy" in section 12-41-103(6) is limited by 12-41-105(1), which states, "Nothing in this article authorizes a physical therapist to perform any of the following acts: (a) practice of medicine, surgery, or ***any other form of healing except as authorized by the provisions of this article***; (b) ... the diagnosis of disease. There is no authorization for acupuncture, or to puncture the skin with an "invasive procedure that breaks the skin of the patient." *See* Chiropractic Memo, cited below.

2. Further, at Section 12-36-106(4), governing medical practice, the General Assembly demonstrated how it intends the interaction between the various health professions should be strictly interpreted: "All licensees designated or referred to in subsection (3) of this section [refer to (3)(m), including all professions not specifically designated], who are licensed to practice a limited field of the healing arts, shall confine themselves strictly to the field for which they are licensed and to the scope of their respective licenses. . . ." In statutory construction, "strictly" cannot be ignored.

(B) The State Board of Physical Therapy ("Board") was ***not*** given broad authority to ***expand the scope of practice*** for physical therapy, but only authority "to adopt all reasonable and necessary rules for the administration and enforcement of this article." A new scope of practice, such as dry needling, is not within the Board's purview of either "administration" or enforcement."

(C) Numerous statements are conclusory, without references, without any supporting information to inform the reader about where there might be information to substantiate the result reached. A conclusion requires facts – not evident when the

reader constantly asks "where does this come from?"

(D) Filoform needles, as used in dry needling, are acupuncture needles regulated by the FDA as medical devices for the practice of acupuncture as "a device intended to pierce the skin in the practice of acupuncture." 21 CFR § 880.5580.

(E) The Rule 211 Memo does not even accurately reference Rule 211, as it more than once states that dry needling by physical therapists is for the relief of pain, or limited to pain relief, but the Rule allows dry needling for additional, other purposes.

(F) ***Contrary to specific authority granted by statute to other health professionals, the Physical Therapists Practice Act does not authorize any device, procedure or function that breaks the skin*** (except wound debridement[1] on a doctor's order, which the statute specifically allows and excepts from the physical therapist surgery prohibition, *see* Section 12-41-113, C.R.S.). ***Notably, other health professions, in addition to acupuncturists, have specific statutory authority for piercing the skin*** and/or practicing acupuncture: chiropractors have authority to puncture a vein (*see* Section 12-33-102 (4), C.R.S.), and to treat by acupuncture, if trained (*see* Section 12-33-102 (1.7), C.R.S.); and a physician does not need a license to render acupuncture services, if trained, (*see* 12-36-106 (3)(p), C.R.S.). *See also* Chiropractic Memo, cited below.

(G) There were significant, not "minor," changes from the 2007 version of Rule 211, to the 2012 Rule 211 with regard to education requirements for dry needling. Under the new version, a physical therapist need only be enrolled in training, and need not complete that training, in order to have authority to conduct dry needling.

(H) The only rule expanding the scope of the physical therapist's practice is one on Animal Physical Therapy (Rule 210) that was ***specifically authorized by statute*** at 12-41-103.6(2)(b)(II) C.R.S. In that Rule, a physical therapist must complete a minimum of 80 hours of education plus 120 hours of clinical experience. Thus, to treat our pets, the Physical Therapy Board requires 5 times as many hours of training and clinical work than to treat a human with a practice technique that is not authorized by statute.

(I) In a publication by American Physical Therapy Association ("APTA"), in documents received pursuant to our open records act request, APTA cites the World Health Organization referring to dry needling in acupuncture. The Rule 211 Memo conclusions to Western versus oriental methods of practice are not accurate. The conclusions in this regard are unsupported.

(J) The Rule 211 Memo does not even address the Rule's **requirement** for physical therapists to perform **diagnosis** as part of dry needling (Rule 211A), which is ***barred*** by the physical therapist practice act and therefore contrary to the statute, section 12-41-105(1)(b), C.R.S. The Board's expanding the practice with diagnosis included is, in itself alone, sufficient to takes Rule 211 outside of the statutory authority of the Board.

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[1] Debridement is the cutting away of dead or contaminated tissue or foreign material from a wound to prevent infection. *Webster's New World College Dictionary 4th Ed.*

December 2012 Chiropractic Rule 7C Memorandum

Compare the Rule 211 Memo analysis and statements to that contained in the Chiropractic Rule 7C Memorandum of December 27, 2012 ("Chiropractic Memo").

(1) In that Chiropractic Memo, the various statutory terms included, among others, "adjustment or manipulation, by hand or by instrument," "use of procedures to facilitate," "use of physical remedial measures for the promotion, maintenance, and restoration of health, the prevention of disease, and the treatment of human ailments... ."

(2) These terms were not broad enough to allow within the statute, a rule authorizing "an invasive procedure that breaks the skin of the patient."

(3) The Rule had been authorized by the Chiropractic Board, but was determined to have exceeded the authority of the Board to issue that rule, despite two instances of statutory authority for a Chiropractor to break the skin – venipuncture and acupuncture.

Specific Comments on the Rule 211 Memo

Below are our comments on the OLLS Memorandum on behalf of the Acupuncture Association of Colorado, inserted into the text of the Rule 211 Memorandum in **blue** text, referencing the letter comment above, and with additional notations, as necessary.

In addition, pursuant to an open records act request, your office provided emails, and related documentation on this rule review. We will provide comments and concerns on issues arising in those documents in a separate writing.

As it is clear that our submission was not utilized in the review and analysis by OLLS, we attach a full copy with this submission for ease of reference and full explanation of our comments.

Copies of this Memorandum and its attachments may be distributed by the Acupuncture Association of Colorado, or its representatives, to additional persons not named above.

MEMORANDUM

Date: March 28, 2013

To: Dan Cartin, OLLS

From: Anne McGihon
Peggy Toal

Cc: Leo Boyle

Re: **Objections to OLLS Memorandum on Rule 211, State Board of Physical Therapy**

Below are our comments on the OLLS Memorandum on behalf of the Acupuncture Association of Colorado, inserted into the text of the Memorandum in **blue** text.

Letters **(A), (B), (C), (D), (E), (F), (G), (H), (I),** and **(J)** refer to and incorporate by reference the corresponding paragraphs in the Summary of Objections Memorandum to which this is attached.

March 8, 2013

MEMORANDUM

TO: Committee on Legal Services

FROM: Chuck Brackney, Office of Legislative Legal Services

RE: Rules of the State Physical Therapy Board, Department of Regulatory Agencies, concerning physical therapists, 4 CCR 732-1[1]
(LLS Docket No. 120310; SOS Tracking No. 2012-00318).

Summary of Problem Identified and Recommendations

The practice of dry needling authorized by Rule 211 of the State Physical Therapy Board is within the scope of practice of physical therapists as set forth in the "Physical Therapy Practice Act." Section 12-41-103 (6), C.R.S., authorizes the use of physical agents and devices for preventive and therapeutic purposes. **This statement is not supported by the discussion below.** **We therefore recommend that the committee take no action regarding Rule 211.** **We disagree.**

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[1] Under section 24-4-103, C.R.S., the Office of Legislative Legal Services reviews rules to determine whether they are within the promulgating agency's rule-making authority. Under section 24-4-103 (8) (c) (I), C.R.S., the rules discussed in this memo will expire on May 15, 2013, unless the General Assembly acts by bill to postpone such expiration.

Analysis

In October 2007, the Colorado Physical Therapy Rules and Regulations were amended to add Rule 11. At that time, authority to adopt this rule rested with the Director of the Division of Registrations ("Director") in the Department of Regulatory Agencies.[2]

Rule 11 established practice guidelines for physical therapists to include use of a treatment intervention known as intramuscular stimulation, commonly referred to as "dry needling" or "trigger point dry needling." This is a treatment procedure in which solid filoform needles (D), as used in acupuncture, are inserted into the skin and muscle at certain trigger points in order to relieve pain (E) by stimulating these points. The rule established minimum standards (H) regarding education (G) also noted by a PT Board member that physical therapists do not meet the minimum requirement (*see* Board materials for November 2012 hearing), training, and patient consent to govern the practice of dry needling by Colorado physical therapists.

In 2011, the General Assembly enacted S.B. 11-169, which transferred rule-making authority regarding the practice of physical therapy from the Director to a newly-created State Board of Physical Therapy ("Board"). Note that this Practice Act was under sunset review in 2010, and the General Assembly did not elect to include dry needling within the scope of Physical Therapy practice. The Board adopted the previous version of the dry needling rule as Rule 211, with minor changes These are not minor changes – a blacklined version of the Rule was made available to OLLS, and the final Rule contained substantial changes to the education and training standards. The current version of Rule 211 is attached as **Addendum A** and a blacklined version is also attached.

The Board is given broad (A), (B) rulemaking power in section 12-41-103.6, C.R.S., which reads as follows:

> **12-41-103.6. Powers and duties of board - reports - publications - rules - repeal.** (2) In addition to any other powers and duties given the board by this article, the board has the following powers and duties:
>
> (b) To adopt **all reasonable and necessary rules for the administration and enforcement of this article** (A), (B), including rules regarding:
>
> (I) The supervision of unlicensed persons by physical therapists, taking into account the education and training of the unlicensed individuals; and
>
> (II) Physical therapy of animals, including, without limitation, educational

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[2] At the time of the initial adoption of Rule 11, no memorandum was provided to the Chair of the Committee on Legal Services according to OLLS staff. Emails from OLLS staff indicate that the review was "a close call," that a memo was written, that staff initially was going to make a presentation to the Committee on Legal Services, "but decided not to," and the Committee on Legal Services never had a legal analysis for review and consideration regarding the initial Rule.

and clinical requirements for the performance of physical therapy of animals and the procedure for handling complaints to the department of regulatory agencies regarding physical therapy of animals. In adopting such rules, the board shall consult with the state board of veterinary medicine established by section 12-64-105. (**emphasis added**) (H)

The Board is granted authority to adopt "all reasonable and necessary rules" regarding the administration of the "Physical Therapy Practice Act" ("Act"). (A), (B).

Statutory authority for a rule that allows physical therapists to engage in dry needling can be found in the Act in section 12-41-103 (6) (A), **nowhere in this section is there authority for dry needling**, C.R.S, establishes the definition of "physical therapy" for purposes of the Act:

12-41-103. Definitions.[3] As used in this article, unless the context otherwise requires:

(6) (a) (I) "Physical therapy" means the examination, treatment, or instruction of patients and clients to detect, assess, prevent, correct, alleviate, or limit physical disability, movement dysfunction, bodily malfunction, or pain from injury, disease, and other bodily conditions.

(II) For purposes of this article "physical therapy" includes:

(C) The use of physical agents, measures, activities, and devices for preventive and therapeutic purposes, subject to the requirements of section 12-41-113; (**emphasis added**)

The statutory definition of the term "physical therapy" includes the use of physical agents, measures, and devices for therapeutic purposes. The Act goes on to define "physical agents" and "physical measures, activities, and devices" at section 12-41-103 (6) (b), C.R.S.:

12-41-103. Definitions. As used in this article, unless the context otherwise requires:

(6)(b) For the purposes of subparagraph (II) of paragraph (a) of this subsection (6):

(I) "**Physical agents" includes, but is not limited to**, heat, cold, water, air, sound, light, compression, electricity, and electromagnetic energy.

(II)(A) "**Physical measures, activities, and devices" includes, but is not limited to**, resistive, active, and passive exercise, with or without devices; joint mobilization; **mechanical stimulation**; biofeedback; postural drainage; traction; positioning; massage; splinting; training in locomotion; other functional activities, with or without assistive devices; and correction of posture, body mechanics, and gait. (**emphasis added**)

The definition of "physical measures, activities, and devices" includes mechanical stimulation, which can include the kind of stimulation of muscles that the technique of dry needling employs. (C) **The author of this Memorandum had to jump to reach this**

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[3] **Nothing in these definitions includes a technique, device, or method that punctures the skin in any way, with the wound debridement exception noted in (F).**

conclusion and go outside of both the statute and the Rule to reach this conclusion. *Compare* Chiropractic Memo. The use of needles to palpate trigger points can be reasonably seen as the use of a "device" (F) to accomplish "mechanical stimulation". (C) A quick review of the physical therapy literature confirms that "mechanical stimulation" does NOT refer to dry needling. *See* attached reference summaries.

The definition of "physical therapy" in section 12-41-103 (6), C.R.S., is broad, expansive and non-specific (A), (B), (C), (F) no practice act is expansive but is restricted and specific to reflect that authority granted its licensed practitioners, and includes a wide range of treatment options (A), (B), (C), (F). Besides the use of "physical agents, measures, activities, and devices", physical therapists may also engage in planning and evaluating treatment and test results, the administration of topical medicines, and general wound care, which includes the "management of skin lesions, surgical incisions, open wounds..." (F), management of such skin issues does not authorize piercing the skin by the Physical Therapist.

Further evidence of this can be seen in the definition of "physical agents" which includes the use of electricity and electromagnetic energy (F). In the practice of physical therapy, this energy is commonly delivered through the use of needles placed at certain points under the skin in the muscle (C), (F) it is not in the statute, and there is no reference, a practice similar in many respects to dry needling. (C)

Finally, although dry needling is not specifically mentioned in this list, the statute expressly maintains that the list is not inclusive. (A), (B), (F), (J) But it is not reasonable to conclude that diagnosis followed by piercing the skin with an acupuncture needle is within the statute when (i) diagnosis is prohibited and (ii) no other such device that pierces the skin is listed. The use of the phrase "includes, but is not limited to" allows for the use of other techniques by physical therapists to accomplish goals usually associated with physical therapy, such as pain relief (E). It is reasonable to conclude that the practice of dry needling to stimulate muscles to relieve pain (E) can be viewed as the use of a physical measure, activity, or device contemplated by section 12-41-103 (6)(b), The complete text of section 12-41-103 (6), C.R.S., is attached as **Addendum B**.

There is some question as to whether dry needling should be considered acupuncture under Colorado law. (A), (B), (C), and *see* discussion in APTA document, as well as attachments to our Memorandum of February 12, 2013. APTA states there is overlap, and others state dry needling is acupuncture. If it were to be considered strictly as acupuncture, then the director would not have the authority to adopt Rule 211. The law dealing with the licensing and practice of acupuncturists in section 12-29.5-102 (1), C.R.S., defines the "acupuncture" as follows:

12-29.5-102. Definitions. As used in this article, unless the context otherwise requires:[4]

(1) "Acupuncture" means a system of health care based upon traditional oriental medical concepts that employs **oriental methods of diagnosis, treatment, and adjunctive therapies** for the promotion, maintenance, and restoration of health and the prevention of disease.

(3.5) "Practice of acupuncture" means the insertion and removal of acupuncture needles (D), the application of heat therapies to specific areas of the human body, and traditional oriental adjunctive therapies. Traditional oriental adjunctive therapies within the scope of acupuncture may include manual, mechanical, thermal, electrical, and electromagnetic treatment, the recommendation of oriental therapeutic exercises, and, subject to federal law, the recommendation of herbs and dietary guidelines. The "**practice of acupuncture" shall be defined by traditional oriental medical concepts and shall not include the utilization of western medical diagnostic tests and procedures**, such as magnetic resonance imaging, radiographs (X-rays), computerized tomography scans, and ultrasound. "Practice of acupuncture" does not mean:

(a) Osteopathic medicine and osteopathic manipulative treatment;

(b) "Chiropractic" or "chiropractic adjustment" as defined in section 12-33-102 or therapies allowed as part of the practice of chiropractic or chiropractic adjustment;

(c) **Physical therapy as defined in section 12-41-103 or therapies allowed as part of the practice of physical therapy**. (emphasis added) **Note discussion below.**

Section 12-29.5-102 (1), C.R.S., establishes that "acupuncture" means a system of health care based on "traditional oriental medical concepts that employs oriental methods of diagnosis, treatment, and adjunctive therapies" for the promotion and restoration of health. By contrast, Rule 211 A. specifies that dry needling "is based on Western medical concepts; requires an examination and diagnosis (J); and treats specific anatomic entities selected according to physical signs". **(A), (B), (C), and *see* attachments to our Memorandum of February 12, 2013.**

The use of dry needling is an extension of recognized physical therapy practice by licensed medical professionals. **(A), (B), (C) And, physical therapists are not licensed medical professionals, as only M.D.s and D.O.s are "medical professionals" under Colorado statute.** It is yet another method that can be used to target and relieve specific tight nodules in a patient's muscles. **(A), (B), (C), (F) not authorized to conduct "an invasive procedure that punctures the skin" *See* Chiropractic Memo.** Compare this with the practice of acupuncture, which focuses using needles to correct imbalances in the flow of qi through channels in the body known as meridians. **(C) and further this is not the statutory definition of acupuncture, quoted above.** Also, the use of dry needling is

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[4] **SB13-172, the Sunset Acupuncture Practice Act, has a revised definition of acupuncture.**

limited to pain relief, (A), (C), (E), while traditional acupuncture can be used to treat a wide range of illnesses and conditions, and can include treatments for weight loss, lowering of blood pressure, anxiety, insomnia, allergies, asthma, skin disorders, and smoking cessation in addition to those to help pain. (C)

Finally, section 12-29.5-102 (3.5)(c), C.R.S., specifically says that practices that are included in the definition of physical therapy do not constitute the "practice of acupuncture." If dry needling is authorized under the terms of the "Physical Therapy Practice Act," then it is, by definition, not the practice of acupuncture for purposes of Colorado law as defined in section 12-29.5-102, C.R.S. **(A) This is entirely backwards - In Colorado, the " 'practice of acupuncture ' means the insertion and removal of acupuncture needles," 12-29.5-102(3.5), C.R.S. The statute further states that " 'practice of acupuncture ' does not mean: ... (c) Physical therapy as defined in section 12-41-103 or therapies allowed as part of the practice of physical therapy." And, both the physical therapy practice act, and the medical practice act limit licensees to their scope of practice.**

The scope of practice for physical therapy in Colorado is broadly defined in the Act in section 12-41-103 (6), C.R.S. Modern physical therapy practice includes the use of an expanding variety of physical agents, activities, and devices for preventive and therapeutic purposes. The definition of physical therapy in the Act contemplates the use of these agents and devices and the techniques that employ them. This includes the practice of dry needling by physical therapists. (A), (B), (C)

By adopting Rule 211, the Board has acted within its authority to regulate this activity for the purpose of establishing minimum requirements for training, competency, and patient consent where no such standards **or scope of practice** existed before. (A), (B)

Because the Board has the authority to adopt rules regarding the practice of dry needling (C) by physical therapists based on the definition of "physical agents" and "physical measures, activities, and devices" found in section 12-41-103 (6), C.R.S., Rule 211 of the rules of the Director concerning physical therapists should be extended. (A), (B), (C),

Addendum A

700 Regulatory Agencies
732 Division of Professions and Occupations - State Physical Therapy Board
4 CCR 732-1 PHYSICAL THERAPIST LICENSURE AND PHYSICAL THERAPIST ASSISTANT CERTIFICATION

211. Requirements for Physical Therapists to Perform Dry Needling

Dry needling (also known as Trigger Point Dry Needling) is a physical intervention that uses a filiform needle to stimulate trigger points, diagnose and treat neuromuscular pain and functional movement deficits; is based upon Western medical concepts; requires an examination and diagnosis, and treats specific anatomic entities selected according to physical signs. Dry needling does not include the stimulation of auricular or distal points.

Dry needling as defined pursuant to this rule is within the scope of practice of physical therapy.

A Physical Therapist must have the knowledge, skill, ability, and documented competency to perform an act that is within the Physical Therapist's scope of practice. Except as part of a course of study on dry needling pursuant to paragraph D.2 of this Rule, a Physical Therapist shall not perform dry needling unless competent to do so.

To be deemed competent to perform dry needling, a Physical Therapist must:

have practiced for at least two years as a licensed Physical Therapist; and

have successfully completed a dry needling course of study that consists of a minimum of 46 hours of in-person (i.e. not online) dry needling training.

A provider of a dry needling course of study must meet the educational and clinical prerequisites as defined in this rule, paragraph D above and demonstrate a minimum of two years of dry needling practice techniques. The provider is not required to be a Physical Therapist.

Physical Therapists performing dry needling in their practice must have written informed consent for each patient where this technique is used. The patient must sign and receive a copy of the informed consent form. The consent form must, at a minimum, clearly state the following information:

Risks and benefits of dry needling; and

Physical Therapist's level of education and training in dry needling; and

The Physical Therapist will not stimulate any distal or auricular points during dry needling.

When dry needling is performed, it must be clearly documented in the procedure notes and must indicate how the patient tolerated the technique, as well as the outcome after the procedure.

Dry needling shall not be delegated and must be directly performed by a qualified, licensed Physical Therapist.

Dry needling must be performed in a manner consistent with generally accepted standards of practice, including clean needle techniques, and the guidelines and recommendations of the Centers for Disease Control and Prevention ("CDC").

The Physical Therapist shall supply written documentation, upon request by the Board, which substantiates appropriate training as required by this Rule. Failure to provide written documentation, upon request, is a violation of this Rule, and is prima facie evidence that the Physical Therapist is not competent and not permitted to perform dry needling

Addendum B

12-41-103. Definitions. As used in this article, unless the context otherwise requires:
(6) (a) (I) "Physical therapy" means the examination, treatment, or instruction of patients and clients to detect, assess, prevent, correct, alleviate, or limit physical disability, movement dysfunction, bodily malfunction, or pain from injury, disease, and other bodily conditions.
(II) For purposes of this article "physical therapy" includes:
The administration, evaluation, and interpretation of tests and measurements of bodily functions and structures;
The planning, administration, evaluation, and modification of treatment and instruction;
The use of physical agents, measures, activities, and devices for preventive and therapeutic purposes, subject to the requirements of section 12-41-113;
The administration of topical and aerosol medications consistent with the scope of physical therapy practice subject to the requirements of section 12-41-113;
The provision of consultative, educational, and other advisory services for the purpose of reducing the incidence and severity of physical disability, movement dysfunction, bodily malfunction, and pain; and
General wound care, including the assessment and management of skin lesions, surgical incisions, open wounds, and areas of potential skin breakdown in order to maintain or restore the integumentary system.
(b) For the purposes of subparagraph (II) of paragraph (a) of this subsection (6):
"Physical agents" includes, but is not limited to, heat, cold, water, air, sound, light, compression, electricity, and electromagnetic energy.
(A) "Physical measures, activities, and devices" includes, but is not limited to, resistive, active, and passive exercise, with or without devices; joint mobilization; mechanical stimulation; biofeedback; postural drainage; traction; positioning; massage; splinting; training in locomotion; other functional activities, with or without assistive devices; and correction of posture, body mechanics, and gait.
(B) "Biofeedback", as used in this subparagraph (II), means the use of monitoring instruments by a physical therapist to detect and amplify internal physiological processes for the purpose of neuromuscular rehabilitation.
"Tests and measurements" includes, but is not limited to, tests of muscle strength, force, endurance, and tone; reflexes and automatic reactions; movement skill and accuracy; joint motion, mobility, and stability; sensation and perception; peripheral nerve integrity; locomotor skill, stability, and endurance; activities of daily living; cardiac, pulmonary, and vascular functions; fit, function, and comfort of prosthetic, orthotic, and other assistive devices; posture and body mechanics; limb length, circumference, and volume; thoracic excursion and breathing patterns; vital signs; nature and locus of pain and conditions under which pain varies; photosensitivity; and physical home and work environments.

Attachment 1 – Blacklined Rule 11 marked to show changes made to the 2007 Rule by the 2012 Rule.

700 Regulatory Agencies
732 Division of Professions and Occupations - State Physical Therapy Board
4 CCR 732-1 PHYSICAL THERAPIST LICENSURE AND PHYSICAL THERAPIST ASSISTANT CERTIFICATION

211. Requirements for Physical Therapists to Perform Dry Needling

A. Dry needling **(ALSO KNOWN AS TRIGGER POINT DRY NEEDLING)** is a physical intervention that uses a filiform needle to stimulate trigger points, **DIAGNOSE AND TREAT NEUROMUSCULAR PAIN AND FUNCTIONAL MOVEMENT DEFICITS**; is based upon Western medical concepts; requires an examination and diagnosis, and treats specific anatomic entities selected according to physical signs. Dry needling does not include the stimulation of auricular or distal points.

B. Dry needling as defined pursuant to this rule is within the scope of practice of physical therapy.

C. A ~~physical therapist~~ **PHYSICAL THERAPIST** must have the knowledge, skill, ability, and documented competency to perform an act that is within the ~~physical therapist~~ **PHYSICAL THERAPIST**'s scope of practice. **EXCEPT AS PART OF A COURSE OF STUDY ON DRY NEEDLING PURSUANT TO PARAGRAPH D.2 OF THIS RULE, A PHYSICAL THERAPIST SHALL NOT PERFORM DRY NEEDLING UNLESS COMPETENT TO DO SO**.

D. To be deemed competent to perform dry needling, a ~~physical therapist~~ **PHYSICAL THERAPIST** must ~~meet the following requirements~~:

1. ~~Documented successful completion of a dry needling course of study. The course must meet the following requirements:~~

   ~~a. A minimum of 46 hours of face-to-face IMS/dry needling course study; online study is not considered appropriate training.~~

   ~~b. Two years of practice as a licensed physical therapist prior to using the dry needling technique.~~

   have practiced for at least two years as a licensed Physical Therapist; and

2. have successfully completed a dry needling course of study that consists of a minimum of 46 hours of in-person (i.e. not online) dry needling training.

E. A provider of a dry needling course of study must meet the educational and clinical

prerequisites as defined in this rule, **PARAGRAPH** D~~(1)(a) & (b)~~ **ABOVE** and demonstrate a minimum of two years of dry needling practice techniques. The provider is not required to be a ~~physical therapist~~ **PHYSICAL THERAPIST**.

F. ~~A physical therapist~~ **PHYSICAL THERAPISTS** performing dry needling in ~~his/her~~ **THEIR** practice must have written informed consent for each patient where this technique is used. The patient must sign and receive a copy of the informed consent form. The consent form must, at a minimum, clearly state the following information:

1. Risks and benefits of dry needling**; AND**

2. Physical Therapist's level of education and training in dry needling**; AND**

3. The Physical Therapist will not stimulate any distal or auricular points during dry needling.

~~H.~~**G.** When dry needling is performed ~~this~~**, IT** must be clearly documented in the procedure notes and must indicate how the patient tolerated the technique**,** as well as the outcome after the procedure.

~~I.~~**H.** Dry needling shall not be delegated and must be directly performed by a qualified, licensed Physical Therapist.

~~J.~~**I.** Dry needling must be performed in a manner consistent with generally accepted standards of practice, including clean needle techniques, and ~~standards of the center for communicable diseases~~ **THE GUIDELINES AND RECOMMENDATIONS OF THE CENTERS FOR DISEASE CONTROL AND PREVENTION ("CDC")**.

~~K.~~**J.** The Physical Therapist ~~shall~~ **MUST BE ABLE TO** supply written documentation, upon request by the Board, which substantiates appropriate training as required by this ~~rule~~ **RULE**. Failure to provide written documentation, upon request, is a violation of this ~~rule~~ **RULE**, and is prima facie evidence that the ~~physical therapist~~ **PHYSICAL THERAPIST** is not competent and not permitted to perform dry needling

~~L. This Rule is intended to regulate and clarify the scope of practice for physical therapists.~~

ATTACHMENT 2

Regular Article

Responses to a clinical test of mechanical provocation of nerve tissue in whiplash associated disorder ☆

M. Sterling, J. Treleaven, G. Jull[?2]
Department of Physiotherapy, The University of Queensland, St Lucia, Australia
http://dx.doi.org/10.1054/math.2002.0443, How to Cite or Link Using DOI
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Abstract

Involvement of nerve tissue may contribute to the persistence of pain following a whiplash injury. This study aimed to investigate responses to the brachial plexus provocation test (BPPT) in 156 subjects with chronic whiplash associated disorder (WAD) with and without associated arm pain and 95 asymptomatic control subjects. The range of elbow extension (ROM) and visual analogue scale (VAS) pain scores were measured. Subjects with chronic WAD demonstrated significantly less ROM and higher VAS scores with the BPPT than the asymptomatic subjects ($P<0.001$). These effects occurred bilaterally. Within the whiplash population, subjects whose arm pain was reproduced by the BPPT demonstrated significantly less ROM on both the symptomatic and asymptomatic sides when compared to the whiplash subjects whose arm pain was not reproduced by the BPPT ($P=0.003$) and significantly less ROM and higher VAS scores than those whiplash subjects with no arm pain ($P=0.003$, 0.01). Only the whiplash subjects whose arm pain was reproduced by the BPPT demonstrated differences between the symptomatic and asymptomatic sides. These generalized hyperalgesic responses to the BPPT support the hypothesis of central nervous system hypersensitivity as contributing to persistent pain experienced by WAD patients.

There are no figures or tables for this document.

☆

Michele Sterling, BPhty, MPhty, Grad Dip Manip Physio, PhD candidate, Julia Treleaven, BPhty, Research Assistant, Gwendolen Jull MPhty, Grad Dip Manip Ther, PhD, FACP, Associate Professor, Department of Physiotherapy, The University of Queensland, St Lucia, Australia.
f2
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Innocuous mechanical stimulation of the neck and alterations in heart-rate variability in healthy young adults

Brian Budgell[a,], Fumie Hirano[b,1]
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http://dx.doi.org/10.1016/S1566-0702(01)00306-X, How to Cite or Link Using DOI

Abstract

The present study examined the effects of cervical spinal manipulation, a widely applied form of physical therapy, which involves innocuous mechanical stimulation, on heart rate and heart-rate variability, in a cohort of healthy young adults. Using a cross-over treatment design, with a one-week washout period and, in contrast to a sham procedure, the authentic

manipulation produced significant alterations in both heart rate and measures of heart-rate variability calculated from power spectrum analysis. In particular, there was an increase in the ratio of low-frequency (LF)-to-high-frequency (HF) components of the power spectrum of heart-rate variability, which may reflect a shift in balance between sympathetic and parasympathetic output to the heart.

Keywords

Autonomic nervous system; Heart rate; Heart-rate variability; Spinal manipulation

Effect of varying frequency, intensity, and pulse duration of transcutaneous electrical nerve stimulation on primary hyperalgesia in inflamed rats ☆

Priya Gopalkrishnan, MS, Kathleen A. Sluka, PhD

From the Physical Therapy Graduate Program (Gopalkrishnan, Sluka) and the Neuroscience Graduate Program (Sluka), University of Iowa, Iowa City, IA.

http://dx.doi.org/10.1053/apmr.2000.5576, How to Cite or Link Using DOI

Abstract

Gopalkrishnan P, Sluka KA. Effect of varying frequency, intensity, and pulse duration of transcutaneous electrical nerve stimulation on primary hyperalgesia in inflamed rats. Arch Phys Med Rehabil 2000;81:984-90. Objectives: To examine the effect of varying frequency, intensity, and pulse duration of transcutaneous electrical nerve stimulation (TENS) on primary hyperalgesia (increased response to a noxious stimuli) to heat and

mechanical stimuli induced by carrageenan paw inflammation in rats. Design: Inflammation was induced by injection of 3% carrageenan into the hindpaw. Two frequencies (high, 100Hz; low, 4Hz), 2 intensities (high, motor; low, sensory), and 2 pulse durations (100μsec, 250μsec) were applied for 20 minutes to the inflamed paw. The paw withdrawal latency (PWL) to radiant heat, threshold to mechanical stimuli, and spontaneous pain-related behaviors were measured before and 4 hours after induction of inflammation, after TENS, and at 8, 12, and 24 hours after inflammation. A 3-factor (frequency, intensity, pulse duration) repeated-measures (time) design was used to analyze the changes in PWL. Mechanical threshold and spontaneous pain-related behaviors were compared for frequency, intensity, and pulse duration with a Kruskal-Wallis analysis of variance. Results: For changes in PWL to heat, there was an effect for time ($p = .0001$) and frequency ($p = .0001$), but not for intensity ($p = .45$) or pulse duration ($p = .21$). For changes in mechanical threshold, there was also an effect for frequency ($p = .007$), but not for intensity ($p = .055$) or pulse duration ($p = .058$), after treatment with TENS. High-frequency TENS significantly reduced the primary hyperalgesia to heat and mechanical stimuli when compared with controls receiving no TENS or treatment with low-frequency TENS. High-frequency motor TENS also reduced spontaneous pain-related behaviors for 1 day after treatment. Conclusion: High-frequency TENS reduces primary hyperalgesia to heat and mechanical stimuli for up to 1 day after treatment. In contrast, low-frequency TENS is ineffective in reducing primary hyperalgesia. Varying intensity or pulse duration had no effect on the degree of antihyperalgesia produced by high-frequency TENS.

There are no figures or tables for this document.

Supported by the Arthritis Foundation. TENS units were donated by EMPI.

Journal of Orthopaedic Trauma:
January 2001 - Volume 15 - Issue 1 - pp 54-60
Original Articles

Mechanical Stimulation by External Application of Cyclic T Strains Does Not Effectively Enhance Bone Healing

Augat, Peter; Merk, Josef; Wolf, Steffen; Claes, Lutz

Abstract

Objective: To determine whether an externally induced interfragmentary movement enhan healing process of a fracture under flexible fixation.

Design: Randomized, prospective in vivo animal study with control group. Twenty-four ske Merino sheep were randomly assigned to six groups of four animals, which received cyclic interfragmentary movements of 0.2 and 0.8 millimeters and stimulation frequencies of 1, 5 Hertz, respectively. Twelve animals did not receive any externally applied stimulation and control group.

Setting: Unrestricted stall activity with weight bearing reduced by tenotomy of the Achilles

Interventions: Osteotomy of the tibial diaphysis with three-millimeter gap width fixed with a monolateral, double-bar external fixator. Interfragmentary movement of the osteotomy gap externally induced by a motor-driven actuator unit. Five hundred cycles inducing nonunifor strains within the gap were performed each day.

Main Outcome Measurements: Nine weeks after surgery, the animals were killed, and bor density and callus cross-sectional area were measured with quantitative computed tomogr projectional area was assessed by radiographs, and mechanical stability was determined point bending test.

Results: External stimulation with nonuniform cyclic tensile strains did slightly affect but no enhance the fracture healing process. Varying the stimulation frequency had no influence process. The stimulation with 0.8 millimeter displacement magnitude resulted in a larger p

callus, but a decreased bone mineral density compared with the 0.2-millimeter displaceme
The stimulation had no significant influence on the mechanical properties of the healing bo

Conclusions: Induced cyclic tensile strains did not produce a relevant enhancement of bor
under flexible fixation.

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COPY

February 12, 2013

BY HAND DELIVERY
Chuck Brackney, Esquire
Office of Legislative Legal Services
Colorado General Assembly
200 East Colfax
Denver, CO 80203

Re: Rule 211, State Board of Physical Therapy

Dear Chuck:

Enclosed please find our Memorandum regarding Rule 211, setting forth our reasons why the Rule should not be extended.

As always, please do not hesitate to contact me if you have any questions or need additional information.

Sincerely,

McGihon & Associates, LLC

Anne L. McGihon

cc: Rep. Jeanne Labuda
Rep. Daniel Kagan
Leo Boyle

Enclosures

MEMORANDUM

To: Chuck Brackney, OLLS

From: Anne McGihon
Peggy Toal

Cc: Rep. Jeanne Labuda
Rep. Daniel Kagan
Leo Boyle

Re: **Rule 211, State Board of Physical Therapy**

SUMMARY OF PROBLEM IDENTIFIED

The rule presented for review is Rule 211 of the State Board of Physical Therapy, promulgated under the Physical Therapy Practice Act, 12-41-101 *et seq*, C.R.S.

Section 12-41-103, C.R.S, defines the scope of practice for a physical therapist. The definition does not authorize physical therapists to perform dry needling. Contrary to authority granted to other health professional, the Physical Therapists Practice Act does not authorize any procedure or function that breaks the skin (except wound debridement[1] on a doctor's order, which the statute specifically allows and excepts from the physical therapist surgery prohibition, *see* Section 12-41-113, C.R.S.).

Nonetheless, Rule 211 of the State Board of Physical Therapy authorizes "dry needling" which requires penetration of the skin with a filiform (acupuncture) needle. It is clear that dry needling is acupuncture.

The Rule establishes a new and lesser regulation of study to be completed before performing dry needling. In addition, Rule 211, as promulgated in 2012, differs from its predecessor rule in that it allows students to perform dry needling prior to completing the minimum course of study and with no requirement for supervision prior to completing the minimum requirements. In doing so, the Board ignored the recommendations set forth in the October 2010 sunset review report, ***Attachment 1***, relating to clarifying and toughening the standards for course work for physical therapists related to dry needling.

The Rule at 211 A includes a requirement of "diagnose" which is specifically prohibited by the Physical Therapist Practice Act, Section 12-41-105, C.R.S. The Rule is well outside the Physical Therapy Practice Act.

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[1] Debridement is the cutting away of dead or contaminated tissue or foreign material from a wound to prevent infection. *Webster's New World College Dictionary 4th Ed.*

Rule 211 is the only Rule promulgated by the State Board of Physical Therapy that authorizes a physical therapist to perform a function not specifically authorized by statute (e.g., animal physical therapy).

For these reasons, and as set forth below, the Rule should not be extended. The Rule should be included in SB13-079 by amendment.

ANALYSIS

Specific Authority Granted to Other Health Professionals Absent from Physical Therapist Practice Act. In Colorado, the " 'practice of acupuncture ' means the insertion and removal of acupuncture needles, [2]" 12-29.5-102(3.5), C.R.S. The statute further states that " 'practice of acupuncture ' does not mean: ... (c) Physical therapy as defined in section 12-41-103 or therapies allowed as part of the practice of physical therapy."

We submit that dry needling is not a therapy contemplated by Section 12-41-103, as it requires piercing the skin with an acupuncture needle. *See e.g.* ***Attachment 2***, photograph from *Dry Needling in the Management of Musculoskeletal Pain*, Kalichman L, Vuffsons S, *J Am Board Fam Med, Sept- Oct 2010, Vol 23:5:640-646.* But if dry needling were considered a therapy under Section 12-41-103, then acupuncturists would be barred from their own profession. Certainly, the Colorado General Assembly's intentions in regulating both physical therapists and acupuncturists must be read to prohibit physical therapists from the practice of acupuncture under Section 12-29.5-101 *et seq.*

In fact, the General Assembly has already delineated what type of care constitutes "western medical diagnostic tests and procedures" in the Acupuncture Practice Act. 12-29.5-102(3.5), C.R.S. Dry needling is not included in the type of care at 12-29.5-102(3.5). Had the General Assembly wanted to include dry needling as a "western medical concept," it had the opportunity to do so in 2011, when it re-enacted the Physical Therapy Practice Act.

Notably, other health professions, in addition to acupuncturists, have specific statutory authority for piercing the skin and/or practicing acupuncture: chiropractors have authority to puncture a vein Section 12-33-102 (4), C.R.S., and to treat by acupuncture, if trained (*see* Section 12-33-102 (1.7)), C.R.S.; and a physician does not need a license to render acupuncture services, if trained, (*see* 12-36-106 (3)(p)), C.R.S. It is notable that physical therapists do not have statutory authority to pierce the skin, rather, as fully discussed below, the profession is restricted by both the definition of the practice of physical therapy and the prohibitions contained in Section 12-41-105, C.R.S.

At Section 12-36-106(4), governing medical practice, The General Assembly demonstrated how it intends the interaction between the various health professions should be strictly interpreted.

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[2] Acupuncture needles are regulated by the FDA and are defined, in part, as "a device intended to pierce the skin in the practice of acupuncture." 21 CFR § 880.5580.

All licensees designated or referred to in subsection (3) of this section [refer to (3)(m), including all professions not specifically designated], who are licensed to practice a limited field of the healing arts, shall confine themselves strictly to the field for which they are licensed and to the scope of their respective licenses. . . .

Rule 211 is a clear extension of the practice area of the physical therapist without statutory authority to do so. In addition, while there is not a ***specific*** statutory ban within the Physical Therapy Practice Act, 12-41-101 *et seq*, C.R.S, prohibiting a physical therapist from performing dry needling, there need not be a specific ban for the Rule to be beyond the statutory authority of the State Board of Physical Therapy. Section 24-4-103 (8)(a), C.R.S., states, "*A rule shall not be deemed to be within the statutory authority and jurisdiction of any agency merely because such rule is not contrary to the specific provisions of a statute.*"

Rule 211. Rule 211 is a rule promulgated in November 2012[3], by the State Physical Therapy Board, based on a prior and similar rule, and is to be reviewed *de novo*. Rule 211 of the Physical Therapy Board authorizes the procedure of "dry needling." (***Attachment 3*** hereto is a redlined version of Rule 211 as proposed in May 2012.)

The Rule provides:

A. Dry needling (also known as Trigger Point Dry Needling) is **a physical intervention that uses a filiform needle[4] to stimulate trigger points, diagnose and treat** neuromuscular pain and functional movement deficits; is based upon western medical concepts; **requires an examination and diagnosis,** and treats specific anatomic entities selected according to physical signs. Dry needling does not include the stimulation of auricular or distal points."

B. Dry needling as defined pursuant to this rule is within the scope of practice of physical therapy.

C. A Physical Therapist must have the knowledge, skill, ability, and documented competency to perform an act that is within the Physical Therapist's scope of practice. Except as part of a course of study on dry needling pursuant to paragraph D.2 of this Rule, a Physical Therapist shall not perform dry needling unless competent to do so.

D. To be deemed competent to perform dry needling, a Physical Therapist

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[3] *See* Appendix A, outlining the promulgation of the Board's Rules.

[4] A filiform needle is defined by *Jonas: Mosby's Dictionary of Complementary and Alternative Medicine.* © 2005, Elsevier, as "solid, extremely fine, stainless steel needle commonly used in acupuncture." Images and examples of a filiform needle derived from a Google search is ***Attachment 4.***

must:

1. have practiced for at least two years as a licensed Physical Therapist; and
2. have successfully completed a dry needling course of study that consists of a minimum of 46 hours of in-person (*i.e.* not online) dry needling training.

E. A provider of a dry needling course of study must meet the educational and clinical prerequisites as defined in this rule, paragraph D above and demonstrate a minimum of two years of dry needling practice techniques. The provider is not required to be a Physical Therapist.

F. Physical Therapists performing dry needling in their practice must have written informed consent for each patient where this technique is used. The patient must sign and receive a copy of the informed consent form. The consent form must, at a minimum, clearly state the following information:

1. Risks and benefits of dry needling; and
2. Physical Therapist's level of education and training in dry needling; and
3. The Physical Therapist will not stimulate any distal or auricular points during dry needling.

G. When dry needling is performed, it must be clearly documented in the procedure notes and must indicate how the patient tolerated the technique, as well as the outcome after the procedure.

H. Dry needling shall not be delegated and must be directly performed by a qualified, licensed Physical Therapist.

I. Dry needling must be performed in a manner consistent with generally accepted standards of practice, including clean needle techniques, and the guidelines and recommendations of the Centers for Disease Control and Prevention ("CDC").

J. The Physical Therapist shall supply written documentation, upon request by the Board, which substantiates appropriate training as required by this Rule. Failure to provide written documentation, upon request, is a violation of this Rule, and is prima facie evidence that the Physical Therapist is not competent and not permitted to perform dry needling [sic]

The Rule, however, is lacking. To say "stimulate trigger points" does not exempt physical therapists from the fact that by this Rule the Board is expanding the practice

beyond the statute by allowing piercing of the skin with this acupuncture technique. *See* Coalition for Safe Acupuncture Practice, *When is Dry Needling Acupuncture? The Short Answer is Always,* ***Attachment 5***. To say "based upon western medical concepts" does not effectively remove the technique from the definition of the practice of acupuncture. *See* American Association of Acupuncture & Oriental Medicine, *Position Statement on Trigger Point Dry Needling (TDN) and Intramuscular Manual Therapy (IMT), May 17, 2011,* ***Attachment 6***. The Rule fails to establish who conducts the "examination and diagnosis," important because physical therapists are prohibited from diagnosis (*see* discussion of Section 12-41-105 C.R.S., below) and it requires diagnosis in another clause of subsection A, which is prohibited.

The Rule as promulgated in 2012 changes the requirements relating to education in at least two ways. The requirement that prior to performing any dry needling, a physical therapist complete the minimum course of study has been removed. Now, the Rule allows anyone who has enrolled in a course of study, but not necessarily completed that course, to perform dry needling with no requirement for any supervision. Second, the requirement that "documented successful completion of a dry needling course of study" prior to performing dry needling has been removed. Instead, a physical therapist must supply written documentation only upon request by the Board of "which substantiates appropriate training as required by the Rule."

In the statutory definition of "device" within the scope of practice of a physical therapist (*see* Section 12-41-103(6)(b)(II)(A) C.R.S., below), there is no device or technique that contemplates piercing of the skin. Further, neither the old rule nor the new Rule 211 addresses the fact of treatment needles being medical devices. *See* 21 CFR 880.5530 *et seq.* Needles are not included in the definitions included at Section 12-41-103 (6) for devices or modalities. Even administration of medication, which must be prescribed by a licensed and authorized health care provider, is restricted to topical and aerosol types, which of course are superficial to the skin. *See* Section 12-41-103(6)(a(II)(D).

Additionally, merely stating, at Rule 211 B, that "dry needling" is within the scope of practice of physical therapy does not make it true, nor does it make it true that it is within the scope of the Physical Therapy Practice Act.

"Trigger Points" and "Western Medical Concepts" Fail to Distinguish Dry Needling from Acupuncture. In a 1976 article entitled *Acupuncture Loci: A Proposal for Their Classification According to Their Relationship to Known Neural Structures,*[5] Dr. Chan Gunn stated, "[a]s a first step toward the acceptance of acupuncture by the medical profession, it is suggested that a new system of acupuncture loci nomenclature be introduced, relating them to known neural structures." Dr. Gunn is the founder of dry needling in Canada.

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[5] Gunn CC, Ditchburn FG, King MH, Renwick GJ, *Acupuncture Loci: A Proposal for Their Classification According to Their Relationship to Known Neural Structures, Am J Chin Med, 1976 Summer; 4(2): 183-95.*

Some have noted that Dr. Gunn "stressed that many trigger points were close to or identical to acupuncture points. Mr. [sic] Gunn believed that Western practitioners would better accept the technique if the point locations were described in anatomical rather than traditional Chinese medical terms." *See, e.g., Letter dated December 15, 2009*, to State of Oregon Medical Board from Rick A. Cigel, Counsel, Allied Professionals Insurance Company, ***Attachment 7*** ("Cigel Letter"). The Cigel Letter explained denial of malpractice insurance to physical therapists performing dry needling, based upon lack of statutory authority and hazards to the public.

The Council of Colleges of Acupuncture and Oriental Medicine in its *Position Paper on Dry Needling* ("CCAOM Position Paper"), ***Attachment 8***, outlined the history of dry needling and the fact that it is essentially a subtopic within acupuncture. Dr. Janet Travell coined the phrase "trigger point" in the early 1980s, a physiological phenomenon long known to acupuncturists. In his book, *A New American Acupuncture*[6], Dr. Mark Seem discussed the similarity of acupuncture and dry needling; and other acupuncturists/authors specializing in sports medicine have noted that they use the trigger point phraseology but teach technique only to licensed acupuncturists.

Since 1976, others have adopted Dr. Gunn's adaption of acupuncture nomenclature to western terms, and attempted to argue that dry needling is a new emerging western technique, when it is not. Yet, there can be no other conclusion than that dry needling is piercing the skin with an acupuncture needle, and it is acupuncture. *See* history, education requirements and evidence in CCAOM Position Paper and Cigel Letter, in full.

In a paper reviewing acupuncture and dry needling risks, two Australian authors stated:

> Based on the similarities between acupuncture and dry needling, the extensive literature on the serious risks of acupuncture is extrapolated to evaluate the risks of dry needling. **Dry needling is not a new or separate practice to acupuncture; rather it is a subsystem of musculoskeletal acupuncture which has been practiced for at least 1400 years. Dry needling is a pseudonym for a brief course of study in myofascial acupuncture also known as *ashi* acupuncture and trigger point acupuncture.** Dry needling is likely to result in an increased incidence of serious risks, particularly pneumothorax due to the short training courses and deep needling techniques which typify the practice. In the interest of public health and safety, the practice of dry needling should be restricted to suitably qualified practitioners.[7]

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[6] *A New American Acupuncture: Acupuncture Osteopathy - The Myofascial Release of the Bodymind's Holding Patterns.* Blue Poppy Press, 1993.

[7] *Acupuncture by Another Name: Dry Needling in Australia*, Janz S, Adams J, Aust J Acupunct Chin Med 2011:6(2);3-11, ***Attachment 9***.

The literature establishes that dry needling ***is*** acupuncture. Use of substitute terms, such as "trigger points" and "western medical concepts," does not mean it is ***not*** acupuncture. The General Assembly has stated what acupuncture is, how acupuncture should be regulated, and acupuncture, even by the name of "dry needling," is not included in the Physical Therapy Practice Act of 2011, and the Board should not be allowed to expand the scope of practice beyond that legislated by the General Assembly.

The Physical Therapy Practice Act of 2011. The Physical Therapist Practice Act was re-enacted in 2011 after sunset review in 2010.[8]

Physical Therapy is defined within the Practice Act at Section 12-41-103, C.R.S.:

> (6) (a) (I) "Physical therapy" means the examination, treatment, or instruction of patients and clients to detect, assess, prevent, correct, alleviate, or limit physical disability, movement dysfunction, bodily malfunction, or pain from injury, disease, and other bodily conditions.
>
> (II) For purposes of this article "physical therapy" includes:
>
> (A) The administration, evaluation, and interpretation of tests and measurements of bodily functions and structures;
>
> (B) The planning, administration, evaluation, and modification of treatment and instruction;
>
> (C) The use of physical agents, measures, activities, and devices for preventive and therapeutic purposes, subject to the requirements of section 12-41-113;
>
> (D) The administration of topical and aerosol medications consistent with the scope of physical therapy practice subject to the requirements of section 12-41-113;
>
> (E) The provision of consultative, educational, and other advisory services for the purpose of reducing the incidence and severity of physical disability, movement dysfunction, bodily malfunction, and pain; and
>
> (F) General wound care, including the assessment and management of skin lesions, surgical incisions, open wounds, and areas of potential skin breakdown in order to maintain or restore the integumentary system.

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[8] Included in this sunset review was moving from a Director supervised profession to a Board supervised profession.

(b) For the purposes of subparagraph (II) of paragraph (a) of this subsection (6):

(I) "Physical agents" includes, but is not limited to, heat, cold, water, air, sound, light, compression, electricity, and electromagnetic energy.

(II) (A) "Physical measures, activities, and devices" includes, but is not limited to, resistive, active, and passive exercise, with or without devices; joint mobilization; mechanical stimulation; biofeedback; postural drainage; traction; positioning; massage; splinting; training in locomotion; other functional activities, with or without assistive devices; and correction of posture, body mechanics, and gait.

(B) "Biofeedback", as used in this subparagraph (II), means the use of monitoring instruments by a physical therapist to detect and amplify internal physiological processes for the purpose of neuromuscular rehabilitation.

(III) "Tests and measurements" includes, but is not limited to, tests of muscle strength, force, endurance, and tone; reflexes and automatic reactions; movement skill and accuracy; joint motion, mobility, and stability; sensation and perception; peripheral nerve integrity; locomotor skill, stability, and endurance; activities of daily living; cardiac, pulmonary, and vascular functions; fit, function, and comfort of prosthetic, orthotic, and other assistive devices; posture and body mechanics; limb length, circumference, and volume; thoracic excursion and breathing patterns; vital signs; nature and locus of pain and conditions under which pain varies; photosensitivity; and physical home and work environments.

The Department of Regulatory Agencies conducted its sunset review and published its report October 15, 2010. Included in that review was a recommendation "[b]ecause the practice of dry-needling could pose potentially significant harm – to cite an extreme example, an improperly placed needle could puncture a patient's lung – there should be an approval process for entities wishing to offer the training in this procedure." Yet, the Rule does not provide for this recommendation. Instead, as discussed above, regulation of the required education is more vague; and it allows dry needling to be performed by any licensed physical therapist who has practiced two years who is simply enrolled in a course of dry needling study.

Thus, the Physical Therapist Practice Act had intense review and there was ample opportunity to incorporate any new practice modalities, including dry needling, into the Physical Therapist Practice Act. Yet, neither the Physical Therapist Practice Act before 2011, nor the re-enacted Practice Act include any reference to dry needling, trigger point dry needling, or any "physical intervention" that would allow physical therapists to perform procedures that break the skin, or penetrate the epidermis.

Further, Section 12-41-105, C.R.S., specifically prohibits physical therapists from among other things, engaging in other forms of healing, or diagnosis.

12-41-105. Limitations on authority

(1) Nothing in this article authorizes a physical therapist to perform any of the following acts:

(a) Practice of medicine, **surgery, or any other form of healing except as authorized by the provisions of this article**; or

(b) Use of roentgen rays and radioactive materials for therapeutic purposes; the use of electricity for surgical purposes; **or the diagnosis of disease**.

Rule 211 clearly allows physical therapists to diagnose in at least one part of the Rule, and perhaps two places. This is prohibited by Section 12-41-105(1)(b), C.R.S.

Board Actively Expanding Procedures Through Rule Making. Rule 211 stands in its own category among the rules promulgated by the Board. It alone is a rule that addresses a physical therapist practice procedure. Every other procedure is included in the Physical Therapist Practice Act, and defined by statute, rather than by a rule. We submit that Rule 211 is beyond the statute and this fact is evidence of that.

The Physical Therapist Practice Act sets out multiple permissible treatment modalities and procedures as noted above in Section 12-41-103, but does not include dry needling. The Physical Therapist Practice Act also addresses special practice requirements at Section 12-41-113, yet does not include dry needling; the Physical Therapist Practice Act limitations on authority, as noted above, containing the statutory prohibition on diagnosis, are directly contrary to Rule 211's requirement of "examination and diagnosis."

CONCLUSION

For the reasons set forth above, the Rule should not be extended. The Rule should be included in SB13-079 by amendment.

APPENDIX A

RULEMAKING RELATING TO STATE BOARD OF PHYSICAL THERAPY RULE 211

In 2011, the Physical Therapy Practice Act was re-enacted, and modified by changing from a Director to a Board governed practice. Thus, the Director's Rules were repealed, the Board's Rules enacted by emergency action, and further action was taken as outlined below.

What we are unable to ascertain is if there exists a Notice for the May 8, 2012 Board meeting where the Physical Therapist Rules were adopted.

We attach the available online history from the Secretary of State's office (summary plus 4 pages), as well as the Notice for the April 2, 2012 Proposed Rulemaking and November 30, 2012 Proposed Rulemaking, and note the following history:

1. Emergency Action
    a. Repeal of all Physical Therapy Rules by Director dated March 9, 2012
    b. Board adopted all Physical Therapist Rules

2. Notice of Proposed Rule Making and Rulemaking Hearing for Physical Therapists Assistant Rules only dated February 29, 2012 for Hearing on April 2, 2012

3. Adoption of Emergency Rules dated April 2, 2012

4. **Hearing Notice for May 8, 2012 Rulemaking Not Located**

5. Hearing Notice for Rules 101, 102, 212 and 214 and proposed Amendment to Rule 211 dated October 30, 2012 for Hearing on November 30, 2012

6. Action on Rule 211 Withdrawn

History

Displayed Version is 9

CCR Number	Effective Date	Version	AG Opinion	Tracking Number	Filing Type
4 CCR 732-1		1			
4 CCR 732-1	09/13/2006	2	09/13/2006	2006-00835	Admin Change by SOS
4 CCR 732-1	11/02/2007	3	11/02/2007	2007-01234	Admin Change by SOS
4 CCR 732-1	11/30/2007	4	10/29/2007	2007-00886	Permanent Rule
4 CCR 732-1	03/30/2011	5	02/24/2011	2010-01163	Permanent Rule
4 CCR 732-1	03/09/2012	6	03/27/2012	2012-00223	Emergency
4 CCR 732-1	04/02/2012	7	04/12/2012	2012-00346	Emergency
4 CCR 732-1	06/30/2012	8	05/22/2012	2012-00206	Permanent Rule
4 CCR 732-1	01/30/2013	9	12/07/2012	2012-00966	Permanent Rule

ATTACHMENTS TO APPENDIX A

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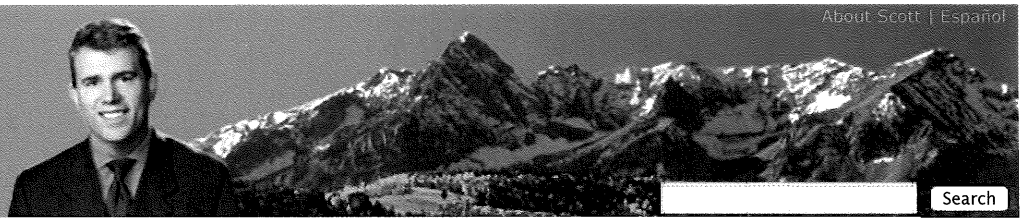
Code of Colorado Regulations eDocket

Details of Tracking Number 2012-00223

Tracking Number	2012-00223
Type of Filing	Emergency
Department	700 Department of Regulatory Agencies
Agency	732 Division of Professions and Occupations - State Physical Therapy Board
CCR Number	4 CCR 732-1
CCR Title	COLORADO PHYSICAL THERAPY LICENSURE RULES AND REGULATIONS
Adopting Agency	
Proposed Rule	
Additional Information	
Comments	The Director repealed all PT Rules on an emergency basis and the newly appointed Physical Therapy Board subsequently adopted all PT Rules.
Public Name	Lisa Hill
Public Title	Program Manager
Public Telephone	303-894-2987
Public Email	lisa.hill@dora.state.co.us
Submitted in response to issues raised by COLS/OLLS?	N
Purpose/Objective of Rule	The basis and purpose of the emergency rules is to implement the requirements of Senate Bill 11-169, as codified in Article 41 of Title 12, C.R.S.
Emergency Justification or Other Document	*EmergencyJustificationPathAttach2012-00223.DOC*
Basis And Purpose	*BasisAndPurposeAttachment2012-00223.DOC*
Statutory Authority	Section 12-41-103.6(1)(a), C.R.S.
Adopted Rules	
	AdoptedRules02012-00223.DOC
Redline	*Redline2012-00223.DOC*
Adopted Date	03/09/2012
Attorney General Opinion	*03/27/2012*
Effective Date	03/09/2012
Inserted into CCR Date	04/11/2012



Code of Colorado Regulations eDocket

Details of Tracking Number 2012-00346

Tracking Number	2012-00346
Type of Filing	Emergency
Department	700 Department of Regulatory Agencies
Agency	732 Division of Professions and Occupations - State Physical Therapy Board
CCR Number	4 CCR 732-1
CCR Title	COLORADO PHYSICAL THERAPY LICENSURE RULES AND REGULATIONS
Adopting Agency	
Proposed Rule	
Additional Information	
Public Name	Lisa
Public Title	Hill
Public Telephone	303-894-2897
Public Email	lisa.hill@dora.state.co.us
Submitted in response to issues raised by COLS/OLLS?	N
Purpose/Objective of Rule	The basis and purpose of the emergency rules is to implement the requirements of Senate Bill 11-169, as codified in Article 41 of Title 12, C.R.S.
Emergency Justification or Other Document	*EmergencyJustificationPathAttach2012-00346.DOC*
Basis And Purpose	*BasisAndPurposeAttachment2012-00346.DOC*
Statutory Authority	Section 12-41-103.6(1)(a), C.R.S.
Adopted Rules	*AdoptedRules02012-00346.DOC*
Redline	*Redline2012-00346.DOC*
Adopted Date	04/02/2012
Attorney General Opinion	*04/12/2012*
Effective Date	04/02/2012
Inserted into CCR Date	04/25/2012

CCR Home
Colorado Register
Colorado Revised Statutes

Search
eDocket

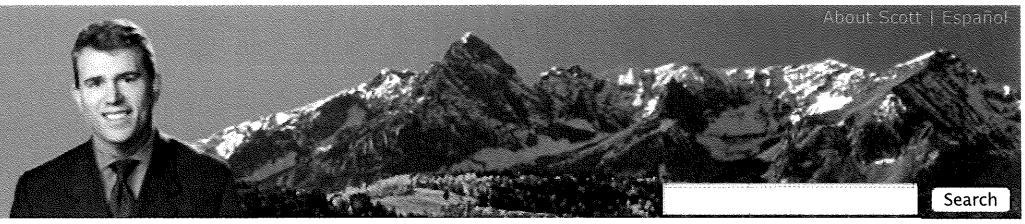
Rulemaking Login
Rule History

Contact Us

Code of Colorado Regulations eDocket

Details of Tracking Number 2012-00206

Tracking Number	2012-00206
Type of Filing	Permanent Rule
Department	700 Department of Regulatory Agencies
Agency	732 Division of Professions and Occupations - State Physical Therapy Board
CCR Number	4 CCR 732-1
CCR Title	COLORADO PHYSICAL THERAPIST LICENSURE & PHYSICAL THERAPIST ASSISTANT CERTIFICATION RULES AND REGULATIONS
Adopting Agency	
Hearing Date	05/08/2012
Hearing Time	09:00 AM
Hearing Location	1560 Broadway, Conference Room 110-D, Denver, CO
Proposed Rule	*ProposedRuleAttach2012-00206.PDF*
Additional Information	*AddInfoAttach2012-00206.PDF*
Description of Subjects/Issues	Rules for the regulation of physical therapists and physical therapy assistants
Comments	NOTE: New Rulemaking Hearing date is 05/08/2012 at 9:00 a.m. in conference room 1250 C. New proposed rules can be found at http://www.dora.state.co.us/physical-therapy/rulemaking.htm NOTE: New Hearing Date of 05/11/2012 is tentative, pending board approval.
Public Name	Lisa Hill
Public Title	Program Manager
Public Telephone	303-894-2987
Public Email	lisa.hill@dora.state.co.us
Submitted in response to issues raised by COLS/OLLS?	N
Purpose/Objective of Rule	The basis and purpose of the rules is to implement the requirements of Senate Bill 11-169, as codified in Article 41 of Title 12, C.R.S. The statutory authority for the rules is found in sections 12-41-201(3), 204, and 206(3)(c), C.R.S.
Basis And Purpose	*BasisandPurposeAttachment2012-00206.DOC*
Statutory Authority	Sections 12-41-201(3), 204, and 206(3)(c), C.R.S.
Adopted Rules	*AdoptedRules02012-00206.DOC*
Adopted Date	05/08/2012
Attorney General Opinion	*05/22/2012*
Effective Date	06/30/2012
Inserted into CCR Date	06/22/2012



CCR Home
Colorado Register
Colorado Revised Statutes

Search
eDocket

Rulemaking Login
Rule History

Contact Us

Code of Colorado Regulations eDocket

Details of Tracking Number 2012-00966

Tracking Number	2012-00966
Type of Filing	Permanent Rule
Department	700 Department of Regulatory Agencies
Agency	732 Division of Professions and Occupations - State Physical Therapy Board
CCR Number	4 CCR 732-1
CCR Title	PHYSICAL THERAPIST LICENSURE AND PHYSICAL THERAPIST ASSISTANT CERTIFICATION
Adopting Agency	
Hearing Date	11/30/2012
Hearing Time	09:00 AM
Hearing Location	1560 Broadway, Conference Room 1250 C Denver, CO 80202
Proposed Rule	*ProposedRuleAttach2012-00966.PDF*
Additional Information	*AddInfoAttach2012-00966.DOC*
Description of Subjects/Issues	The rulemaking concerns the initial proposal of Rules 101, 102, 212, and 214, and proposed amendments to Rule 211. [SEE NOTE BELOW RE RULE 211]
Comments	NOTE: The Physical Therapy Board ("Board") has decided to withdraw consideration of Rule 211 in their rulemaking hearing on 11/30/2012. At its rulemaking hearing on November 30, 2012, the Board adopted rules 101 and 102 without ammendment, and adoopted rules 212 and 214 as amended. At the November 30, 2012, Rulemaking Hearing, the State Physical Therapy Board adopted Rules 101 and 102 without amendment, and adopted Rules 212 and 214 as amended.
Public Name	Lisa
Public Title	Hill
Public Telephone	303-894-2987
Public Email	lisa.hill@state.co.us
Submitted in response to issues raised by COLS/OLLS?	N
Purpose/Objective of Rule	The purpose of this rulemaking is to outline the conditions and procedures governing the evaluation of an applicant's military training and experience, designate a nationally-recognized examination approved by the Board, outline the conditions and procedures governing inactive licensure, and delineate the procedures a licensee must adhere to when an act enumerated in section 12-41-115, C.R.S., has occurred
Basis And Purpose	*BasisandPurposeAttachment2012-00966.DOC*
Statutory Authority	Sections 24-34-102(8.5), 12-41-103.6(2)(b), 12-41-107, 12-41-111, 12-41-112.5, 12-41-205, and 12-41-207C.R.S.
Adopted Rules	*AdoptedRules02012-00966.RTF*
Redline	*Redline2012-00966.RTF*
Adopted Date	11/30/2012
Attorney General Opinion	*12/07/2012*
Effective Date	01/30/2013
Inserted into CCR Date	01/16/2013

Dora
Department of Regulatory Agencies

Division of Registrations
Gregory Ferland
Interim Division Director

State Physical Therapy Board
Deann Conroy
Program Director

John W. Hickenlooper
Governor

Barbara J. Kelley
Executive
Director

Notice of Proposed Rulemaking and Rulemaking Hearing

Pursuant to section 24-4-103 of the Colorado Revised Statutes ("C.R.S."), you are hereby notified that the Board of Physical Therapy ("Board") will be holding a public rulemaking hearing as follows:

Date: April 2, 2012

Time: 9:00 AM

Location: 1560 Broadway
Conference Room 110 D
Denver, Colorado

The rulemaking concerns proposed rules for the regulation of physical therapist assistants. The basis and purpose of the rules is to implement the requirements of Senate Bill 11-169, as codified in Article 41 of Title 12, C.R.S. The statutory authority for the rules is found in sections 12-41-201(3), 204, and 206(3)(c), C.R.S.

Please be advised that the proposed rules may be changed after public comment and formal hearing.

At the time and place stated in this notice, the Board will afford interested persons an opportunity to submit written data, views, or arguments, and to submit the same orally. The Board may limit the time allotted for oral submissions in its discretion. Written submissions should be filed with the Board at least ten (10) days prior to the hearing. All submissions will be considered. Written submissions may be filed at the following address:

State Physical Therapy Board
1560 Broadway
Suite 1350
Denver, CO 80202

Dated this 29th day of February, 2012.

BY ORDER OF THE STATE PHYSICAL THERAPY BOARD

Dino Ioannides
Section Director

Dora
Department of Regulatory Agencies

Division of Professions and Occupations
Lauren Larson
Division Director

State Physical Therapy Board
Deann Conroy
Program Director

John W. Hickenlooper
Governor

Barbara J. Kelley
Executive Director

Notice of Proposed Rulemaking and Rulemaking Hearing

Pursuant to section 24-4-103 of the Colorado Revised Statutes ("C.R.S."), you are hereby notified that the State Physical Therapy Board ("Board") will be holding a public rulemaking hearing as follows:

Date: November 30, 2012

Time: 9:00 AM

Location: 1560 Broadway
Conference Room 1250 C
Denver, Colorado 80202

The rulemaking concerns the initial proposal of Rules 101, 102, 212, and 214, and proposed amendments to Rule 211. The basis and purpose of this rulemaking is to outline the conditions and procedures governing the evaluation of an applicant's military training and experience, designate a nationally-recognized examination approved by the Board, clarify the requirements that must be met in order for a physical therapist to administer dry needling, outline the conditions and procedures governing inactive licensure, and delineate the procedures a licensee must adhere to when an act enumerated in section 12-41-115, C.R.S. has occurred. The statutory authority for the rules is found in sections 24-34-102(8.5), 12-41-103.6(2)(b), 12-41-107, 12-41-111, 12-41-112.5, 12-41-205, and 12-41-207C.R.S.

Please be advised that the proposed rules may be changed after public comment and formal hearing. At the time and place stated in this notice, the Board will afford interested persons an opportunity to submit written data, views, or arguments, and to submit the same orally. The Board may limit the time allotted for oral submissions in its discretion. Written submissions should be filed with the Board at least ten (10) days prior to the hearing. All submissions will be considered. Written submissions may be filed at the following address:

State Physical Therapy Board
1560 Broadway
Suite 1350
Denver, CO 80202

Dated this 30th day of October, 2012

BY ORDER OF THE STATE PHYSICAL THERAPY BOARD

Deann Conroy
Program Director

Dora

Department of Regulatory Agencies

Office of Policy, Research and Regulatory Reform

2010 Sunset Review: Regulation of Physical Therapists

October 15, 2010

Consumer Protection

Attachment 1

Dora
Department of Regulatory Agencies

Executive Director's Office
Barbara J. Kelley
Executive Director

Bill Ritter, Jr.
Governor

October 15, 2010

Members of the Colorado General Assembly
c/o the Office of Legislative Legal Services
State Capitol Building
Denver, Colorado 80203

Dear Members of the General Assembly:

The mission of the Department of Regulatory Agencies (DORA) is consumer protection. As a part of the Executive Director's Office within DORA, the Office of Policy, Research and Regulatory Reform seeks to fulfill its statutorily mandated responsibility to conduct sunset reviews with a focus on protecting the health, safety and welfare of all Coloradans.

DORA has completed the evaluation of the regulation of physical therapists. I am pleased to submit this written report, which will be the basis for my office's oral testimony before the 2011 legislative committee of reference. The report is submitted pursuant to section 24-34-104(8)(a), of the Colorado Revised Statutes (C.R.S.), which states in part:

> The department of regulatory agencies shall conduct an analysis of the performance of each division, board or agency or each function scheduled for termination under this section...
>
> The department of regulatory agencies shall submit a report and supporting materials to the office of legislative legal services no later than October 15 of the year preceding the date established for termination....

The report discusses the question of whether there is a need for the regulation provided under Article 41 of Title 12, C.R.S. The report also discusses the effectiveness of the Division of Registrations and staff in carrying out the intent of the statutes and makes recommendations for statutory changes in the event this regulatory program is continued by the General Assembly.

Sincerely,

Barbara J. Kelley
Executive Director

1560 Broadway, Suite 1550 Denver, Colorado 80202 Phone 303.894.7855
Fax 303.894.7885 Toll Free 800.866.7675 www.dora.state.co.us V/TDD 711

Consumer Protection

Department of Regulatory Agencies

Bill Ritter, Jr.
Governor

Barbara J. Kelley
Executive Director

2010 Sunset Review:
Regulation of Physical Therapists

Summary

What Is Regulated?
Physical therapists (PTs) are healthcare professionals who diagnose and treat individuals whose ability to move and perform basic functions is inhibited due to an illness, injury, or health condition.

Why Is It Regulated?
To assure that PTs meet a standard level of competency.

Who Is Regulated?
In June 2010, there were 6,001 licensed PTs.

How Is It Regulated?
The Director of the Division of Registrations (Director) within the Colorado Department of Regulatory Agencies is vested with the authority to regulate physical therapists. The Physical Therapy Advisory Committee assists the Director in fulfilling his or her statutory responsibilities. In order to qualify for a license to practice physical therapy, applicants must provide evidence that they have completed an accredited physical therapy education program and passed a written examination.

What Does It Cost?
In fiscal year 08-09, the total cost of the PT licensing program was $185,746, and there were 0.7 full-time equivalent employees associated with the program.

What Disciplinary Activity Is There?
From fiscal year 04-05 to 08-09, the Director took a total of 33 disciplinary actions against PTs, including letters of admonition, suspensions, relinquishments, revocations, probations, and injunctions.

Where Do I Get the Full Report?
The full sunset review can be found on the internet at: www.dora.state.co.us/opr/oprpublications.htm.

Key Recommendations

Continue the regulation of physical therapists for seven years, until 2018.
Colorado's licensure program ensures that PTs have the knowledge and skills to practice safely by requiring prospective PTs to meet specific minimum requirements, including completing an accredited education program and passing a comprehensive examination. Through its licensing, rulemaking and disciplinary activities, the PT licensure program protects the public health, safety and welfare of Coloradans.

Re-establish the Board of Physical Therapy and repeal the Physical Therapy Advisory Committee.
Since the last sunset review, in 2000, the profession of physical therapy has undergone significant changes. PT practice has become increasingly independent, and an increasingly complex healthcare environment means that an entry-level PT in 2010 must possess a greater body of knowledge, skills and abilities than an entry-level PT in 2000. These changes have led to more scope of practice questions, and the number of substandard practice complaints has risen steadily. The Director does not have the specific professional expertise to address these matters without assistance; consequently, the Director has increasingly relied upon the Committee's expertise. In essence, although the Director is ultimately the regulatory authority, the Committee has been functioning more and more as a board. For these reasons, the General Assembly should re-establish the Board of Physical Therapy (Board).

Establish that a PT's failure to properly address his or her own physical or mental condition is grounds for discipline, and authorize the Board to enter into confidential agreements with PTs to address their respective conditions. Under current law, the Director may take disciplinary action against a PT who has a physical or mental condition which renders the PT unable to treat patients with reasonable skill and safety. Simply having such a condition should not be grounds for discipline, but failing to limit one's practice to accommodate such a condition should be. The General Assembly should clarify the grounds for discipline accordingly, and grant the newly created Board the authority to enter into confidential agreements with PTs having such conditions.

Major Contacts Made During This Review

Colorado Department of Regulatory Agencies
Physical Therapy Advisory Committee
American Physical Therapy Association, Colorado Chapter
Acupuncture Association of Colorado
Colorado Chiropractic Association
Federation of State Boards of Physical Therapy

What is a Sunset Review?

A sunset review is a periodic assessment of state boards, programs, and functions to determine whether or not they should be continued by the legislature. Sunset reviews focus on creating the least restrictive form of regulation consistent with protecting the public. In formulating recommendations, sunset reviews consider the public's right to consistent, high quality professional or occupational services and the ability of businesses to exist and thrive in a competitive market, free from unnecessary regulation.

Sunset Reviews are Prepared by:
Colorado Department of Regulatory Agencies
Office of Policy, Research and Regulatory Reform
1560 Broadway, Suite 1550, Denver, CO 80202
www.dora.state.co.us/opr

Table of Contents

Background

Introduction

Enacted in 1976, Colorado's sunset law was the first of its kind in the United States. A sunset provision repeals all or part of a law after a specific date, unless the legislature affirmatively acts to extend it. During the sunset review process, the Department of Regulatory Agencies (DORA) conducts a thorough evaluation of such programs based upon specific statutory criteria[1] and solicits diverse input from a broad spectrum of stakeholders including consumers, government agencies, public advocacy groups, and professional associations.

Sunset reviews are based on the following statutory criteria:

- Whether regulation by the agency is necessary to protect the public health, safety and welfare; whether the conditions which led to the initial regulation have changed; and whether other conditions have arisen which would warrant more, less or the same degree of regulation;
- If regulation is necessary, whether the existing statutes and regulations establish the least restrictive form of regulation consistent with the public interest, considering other available regulatory mechanisms and whether agency rules enhance the public interest and are within the scope of legislative intent;
- Whether the agency operates in the public interest and whether its operation is impeded or enhanced by existing statutes, rules, procedures and practices and any other circumstances, including budgetary, resource and personnel matters;
- Whether an analysis of agency operations indicates that the agency performs its statutory duties efficiently and effectively;
- Whether the composition of the agency's board or commission adequately represents the public interest and whether the agency encourages public participation in its decisions rather than participation only by the people it regulates;
- The economic impact of regulation and, if national economic information is not available, whether the agency stimulates or restricts competition;
- Whether complaint, investigation and disciplinary procedures adequately protect the public and whether final dispositions of complaints are in the public interest or self-serving to the profession;
- Whether the scope of practice of the regulated occupation contributes to the optimum utilization of personnel and whether entry requirements encourage affirmative action;
- Whether administrative and statutory changes are necessary to improve agency operations to enhance the public interest.

[1] Criteria may be found at § 24-34-104, C.R.S.

Types of Regulation

Consistent, flexible, and fair regulatory oversight assures consumers, professionals and businesses an equitable playing field. All Coloradans share a long-term, common interest in a fair marketplace where consumers are protected. Regulation, if done appropriately, should protect consumers. If consumers are not better protected and competition is hindered, then regulation may not be the answer.

As regulatory programs relate to individual professionals, such programs typically entail the establishment of minimum standards for initial entry and continued participation in a given profession or occupation. This serves to protect the public from incompetent practitioners. Similarly, such programs provide a vehicle for limiting or removing from practice those practitioners deemed to have harmed the public.

From a practitioner perspective, regulation can lead to increased prestige and higher income. Accordingly, regulatory programs are often championed by those who will be the subject of regulation.

On the other hand, by erecting barriers to entry into a given profession or occupation, even when justified, regulation can serve to restrict the supply of practitioners. This not only limits consumer choice, but can also lead to an increase in the cost of services.

There are also several levels of regulation.

Licensure

Licensure is the most restrictive form of regulation, yet it provides the greatest level of public protection. Licensing programs typically involve the completion of a prescribed educational program (usually college level or higher) and the passage of an examination that is designed to measure a minimal level of competency. These types of programs usually entail title protection – only those individuals who are properly licensed may use a particular title(s) – and practice exclusivity – only those individuals who are properly licensed may engage in the particular practice. While these requirements can be viewed as barriers to entry, they also afford the highest level of consumer protection in that they ensure that only those who are deemed competent may practice and the public is alerted to those who may practice by the title(s) used.

Certification

Certification programs offer a level of consumer protection similar to licensing programs, but the barriers to entry are generally lower. The required educational program may be more vocational in nature, but the required examination should still measure a minimal level of competency. Additionally, certification programs typically involve a non-governmental entity that establishes the training requirements and owns and administers the examination. State certification is made conditional upon the individual practitioner obtaining and maintaining the relevant private credential. These types of programs also usually entail title protection and practice exclusivity.

While the aforementioned requirements can still be viewed as barriers to entry, they afford a level of consumer protection that is lower than a licensing program. They ensure that only those who are deemed competent may practice and the public is alerted to those who may practice by the title(s) used.

Registration

Registration programs can serve to protect the public with minimal barriers to entry. A typical registration program involves an individual satisfying certain prescribed requirements – typically non-practice related items, such as insurance or the use of a disclosure form – and the state, in turn, placing that individual on the pertinent registry. These types of programs can entail title protection and practice exclusivity. Since the barriers to entry in registration programs are relatively low, registration programs are generally best suited to those professions and occupations where the risk of public harm is relatively low, but nevertheless present. In short, registration programs serve to notify the state of which individuals are engaging in the relevant practice and to notify the public of those who may practice by the title(s) used.

Title Protection

Finally, title protection programs represent one of the lowest levels of regulation. Only those who satisfy certain prescribed requirements may use the relevant prescribed title(s). Practitioners need not register or otherwise notify the state that they are engaging in the relevant practice, and practice exclusivity does not attach. In other words, anyone may engage in the particular practice, but only those who satisfy the prescribed requirements may use the enumerated title(s). This serves to indirectly ensure a minimal level of competency – depending upon the prescribed preconditions for use of the protected title(s) – and the public is alerted to the qualifications of those who may use the particular title(s).

Licensing, certification and registration programs also typically involve some kind of mechanism for removing individuals from practice when such individuals engage in enumerated proscribed activities. This is generally not the case with title protection programs.

Regulation of Businesses

Regulatory programs involving businesses are typically in place to enhance public safety, as with a salon or pharmacy. These programs also help to ensure financial solvency and reliability of continued service for consumers, such as with a public utility, a bank or an insurance company.

Activities can involve auditing of certain capital, bookkeeping and other recordkeeping requirements, such as filing quarterly financial statements with the regulator. Other programs may require onsite examinations of financial records, safety features or service records.

Although these programs are intended to enhance public protection and reliability of service for consumers, costs of compliance are a factor. These administrative costs, if too burdensome, may be passed on to consumers.

Sunset Process

Regulatory programs scheduled for sunset review receive a comprehensive analysis. The review includes a thorough dialogue with agency officials, representatives of the regulated profession and other stakeholders. Anyone can submit input on any upcoming sunrise or sunset review via DORA's website at: www.dora.state.co.us/pls/real/OPR_Review_Comments.Main.

The regulation of physical therapists by the Director of the Division of Registrations (Director and Division, respectively) relating to Article 41 of Title 12, Colorado Revised Statutes (C.R.S.), shall terminate on July 1, 2011, unless continued by the General Assembly. During the year prior to this date, it is the duty of DORA to conduct an analysis and evaluation of the Division pursuant to section 24-34-104, C.R.S.

The purpose of this review is to determine whether the currently prescribed regulation of physical therapists should be continued for the protection of the public and to evaluate the performance of the Director and staff of the Division. During this review, the Division must demonstrate that the regulation serves to protect the public health, safety or welfare, and that the regulation is the least restrictive regulation consistent with protecting the public. DORA's findings and recommendations are submitted via this report to the legislative committee of reference of the Colorado General Assembly.

Methodology

As part of this review, DORA staff interviewed the Director and Division staff, attended Physical Therapy Advisory Committee (Committee) meetings, reviewed Committee records and minutes, reviewed complaint and disciplinary actions, interviewed officials with state and national professional associations, observed PTs treating patients, reviewed Colorado statutes and rules, and reviewed the laws of other states.

Profile of the Profession

Physical therapists (PTs) are healthcare professionals who diagnose and treat individuals whose ability to move and perform basic functions is inhibited due to an illness, injury, or health condition. PTs treat people across the lifespan. Potential consumers of physical therapy services include an infant who is unable to sit up due to a developmental delay, a teenager with a sports-related injury, someone who has had knee replacement surgery, and an elderly person who lost physical capabilities following a stroke. PTs seek to increase patients' mobility, strength, and independence, mitigate pain and discomfort, promote wellness, and prevent injury.

PTs may treat patients with therapeutic exercise, manual therapy, adaptive or assistive devices or equipment, or modalities such as heat, cold, ultrasound, or electrical stimulation. PTs often work as part of a rehabilitative healthcare team that includes physicians, nurses, occupational therapists, and speech therapists. PTs work in hospitals, outpatient clinics, private offices, mobile clinics, and in home health.

All 50 states require PTs to be licensed. Though licensing requirements vary from state to state, most states require applicants to complete a doctoral program in physical therapy and pass the National Physical Therapy Examination.

The Bureau of Labor Statistics expects the employment of PTs to grow much faster than the average for all occupations over the next 10 years.[2] The aging of the baby-boom generation, the growing popularity of procedures such as joint replacement, the increasing acuity of people requiring rehabilitative care, and the evolving role of mid-level healthcare providers in the American healthcare system are all likely to fuel demand for the services PTs provide.

[2] Bureau of Labor Statistics. *Occupational Outlook Handbook 2010-11.* Retrieved on June 23, 2010, from http://www.bls.gov/oco/ocos080.htm

Legal Framework

History of Regulation

Colorado began regulating physical therapists (PTs) in 1959, when the Colorado General Assembly created a Colorado State Board of Physical Therapy (Board) within the Secretary of State's Office. The Board was charged with licensing PTs by examination, endorsement, or waiver. At that time, PTs could only provide physical therapy to clients pursuant to a physician's order, and could only practice under physician supervision. The Board consisted of three licensed PTs, all of whom were required to have a minimum of five years of experience either as a practicing PT or as a teacher in an accredited PT education program.

The Administrative Organization Act of 1968 transferred the Board to the Department of Regulatory Agencies (DORA).

In 1971, the Physical Therapy Practice Act (Act) was revised to permit PTs to provide care under the prescription and direction of a licensed dentist, podiatrist, or physician.[3]

In 1977, the General Assembly expanded the Board from three members to five, with the addition of two members representing the public. The statutory language specifically prohibited the two public members from being engaged, directly or indirectly, in the provision of health services.[4]

Senate Bill 79-449 made numerous changes to the Act pursuant to the 1979 sunset review. PTs were granted title protection, and the definition of physical therapy was expanded to include the administration and evaluation of physical therapy tests and the use of medical devices.[5]

The Board underwent sunset again in 1985. Pursuant to a sunset recommendation, Senate Bill 86-11 dissolved the Board and reconfigured PT regulation as a registration program under the authority of the Director of DORA's Division of Registrations (Director and Division, respectively). The bill transferred all powers previously vested in the Board—such as the authority to promulgate rules, and to license and discipline PTs—to the Director; however, it also required the Director to form the Physical Therapy Advisory Committee (Committee) comprised of at least five licensed PTs to help the Director meet his or her statutory responsibilities.[6] Although the bill removed all references to PT "licensing," substituting the term "registration," it did not change the required qualifications for PTs.

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[3] *Sunset Review of the Physical Therapy Practice Act,* Colorado Department of Regulatory Agencies (2000), p.5.
[4] House Bill 77-1244.
[5] *Sunset Review of the Physical Therapy Practice Act,* Colorado Department of Regulatory Agencies (2000), p.5.
[6] Senate Bill 86-11.

The next major change occurred in 1988, when statutory language prohibiting direct access to PTs was repealed:[7] patients no longer had to have a prescription from a physician, dentist, or podiatrist in order to receive physical therapy. Rather, patients could directly seek the services of a PT without going through an intermediary.

House Bill 91-1136 made numerous changes to the Act in light of the 1990 sunset report. The bill reinstated the term "license" to refer to PTs, arguing that this term better described the regulatory model for PTs. The bill revised the definition of physical therapy to reflect current practice more accurately, and expanded the grounds for discipline of a PT license to include, among other things, failure to properly refer patients to the appropriate healthcare provider, patient abandonment, inadequate supervision of unlicensed persons, and offering or receiving commissions or rebates in exchange for the referral of clients. The bill also granted the Director the authority to summarily suspend the license of a PT if there were reasonable cause to believe that the PT cannot practice safely. The bill also increased the number of Committee members from five to seven: five PTs and two individuals with specific healthcare knowledge.

Several changes were made after the 2000 sunset review. Substantive revisions included removing the requirement that PTs perform wound debridement only under the direct supervision of a physician. The legislation also permitted the Division to pay members of the Committee a standard per diem for their service, and removed all references to temporary permits and licenses.[8]

In 2007, the General Assembly passed House Bill 07-1126, which authorized PTs to perform physical therapy on animals, and required the Director to establish, by rule, the minimum educational and clinical requirements PTs must meet before performing such therapy.

Finally, the General Assembly passed two bills affecting PTs during the 2010 session.

Senate Bill 10-124 added PTs to the list of healthcare providers who must provide profile information to the Division pursuant to the Michael Skolnik Medical Transparency Act of 2010. Such information includes, but is not limited to, education and training history, any specialties or certifications, practice location(s), and any disciplinary actions or malpractice settlements.

House Bill 10-1175 revised the statutory language regarding licensing by endorsement to permit the Director to promulgate rules establishing ways for PT endorsement applicants to demonstrate their professional competency.

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[7] Senate Bill 88-11.
[8] Senate Bill 01-113.

Physical Therapy Practice Act

The laws governing PT regulation are housed within Article 41 of Title 12, Colorado Revised Statutes (C.R.S.), and are known collectively as the "Physical Therapy Practice Act" (Act). The Director is vested with the authority to regulate PTs in Colorado.

The primary responsibilities of the Director include:[9]

- Issuing licenses to qualified applicants;
- Adopting all rules necessary for the administration of the Act;
- Conducting hearings and prosecuting individuals who violate the Act;
- Establishing fines and fees, and making necessary expenditures to administer the Act; and
- Promoting consumer protection and education.

The Act requires the Director to appoint the seven-member Committee, which assists in the performance of the Director's duties under the Act. The Committee is comprised of:[10]

- Five licensed PTs; and
- Two members who are not PTs, but possess specific knowledge in the healthcare field.

The Committee must meet at least twice a year. Members receive a standard per diem for their service, and are reimbursed for actual expenses incurred in the performance of their duties.[11]

Scope of Practice

The Act defines physical therapy as:[12]

> ...the examination, treatment, or instruction of patients and clients to detect, assess, prevent, correct, alleviate, or limit physical disability, movement dysfunction, bodily malfunction, or pain from injury, disease, and other bodily conditions.

[9] §12-41-125(2), C.R.S.
[10] § 12-41-126, C.R.S.
[11] § 12-41-126, C.R.S.
[12] § 12-41-103(6)(a)(I), C.R.S.

In assessing patients, PTs may administer, evaluate and interpret tests and measurements.[13] For example, a PT might perform tests to determine:[14]

- Muscle strength, endurance, and tone;
- Joint motion, mobility, and stability;
- Sensation and perception;
- Posture and body mechanics; and
- The nature and locus of any pain the patient is experiencing, and the conditions under which pain varies.

PTs treat patients using physical agents, measures, activities, and devices.[15] Examples of physical agents include:[16]

- Heat;
- Cold;
- Water;
- Light;
- Compression; and
- Electricity.

Examples of measures, activities and devices include:[17]

- Resistive, active, and passive exercise;
- Joint mobilization;
- Massage;
- Training in locomotion and other functional activities, with or without assistive devices; and
- Correction of posture, body mechanics, and gait.

PTs may administer topical and aerosol medications as prescribed by an authorized healthcare practitioner.[18] PTs may also perform wound debridement[19] pursuant to a physician's order.[20]

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[13] § 12-41-103(6)(a)(II)(A), C.R.S.
[14] § 12-41-103(6)(b)(III), C.R.S.
[15] § 12-41-103(6)(a)(II)(C), C.R.S.
[16] § 12-41-103(6)(b)(I), C.R.S.
[17] § 12-41-103(6)(b)(II)(A), C.R.S.
[18] § 12-41-113(2), C.R.S.
[19] Wound debridement is the process of removing dead tissue or foreign material from a wound to expose healthy tissue. This can be performed using enzymes, mechanical devices, chemicals, or surgical devices such as scalpels or scissors. Source: Encyclopedia of Surgery. *Debridement.* Retrieved on September 20, 2010, from http://www.surgeryencyclopedia.com/Ce-Fi/Debridement.html
[20] § 12-41-113(3), C.R.S.

The Director may authorize PTs who meet specific educational and experiential requirements to perform physical therapy on animals. To qualify for such authorization, a PT must complete at least 80 additional hours of coursework and accrue at least 120 hours of practice experience under the supervision of either a PT authorized to perform physical therapy on animals, or a Colorado-licensed veterinarian.[21] PTs must get veterinary medical clearance from a veterinarian before performing physical therapy on an animal.[22]

PTs meeting specific requirements may perform an intervention known as dry-needling. In dry-needling, a PT uses a filiform needle[23] to stimulate trigger points, and diagnose and treat neuromuscular pain and functional movement deficits.[24] In order to perform this intervention, a PT must complete a dry-needling course consisting of at least 46 hours of face-to-face instruction and have two years of experience as a licensed PT.[25]

The law specifically prohibits PTs from practicing medicine or surgery and from diagnosing disease.[26] PTs may not use X-rays or radioactive materials, and may not use electricity for either surgical or lifesaving measures.[27]

Licensing

Colorado has a mandatory practice act, meaning that in order to practice physical therapy, a person must be licensed under the Act.[28] Applicants may apply for licensure by examination or by endorsement.

All applicants must submit an application and pay the required fee.[29]

Applicants for licensure by examination must submit evidence documenting that they:

- Completed a physical therapy program that is either accredited by a nationally recognized agency, or is substantially equivalent to an accredited program;[30] and
- Passed a written examination.[31]

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[21] Colorado Physical Therapy Licensure Rules and Regulations, 4 CCR 732-1, 10.
[22] §12-41-113(4), C.R.S.
[23] A filiform needle is a solid, extremely fine needle commonly used in acupuncture. Retrieved on September 20, 2010, from http://medical-dictionary.thefreedictionary.com/filiform+needles
[24] Colorado Physical Therapy Licensure Rules and Regulations, 4 CCR 732-1, 11A.
[25] Colorado Physical Therapy Licensure Rules and Regulations, 4 CCR 732-1, 11D.
[26] §12-41-105(1), C.R.S.
[27] §12-41-105(1), C.R.S.
[28] § 12-41-106, C.R.S.
[29] §§ 12-41-107(1)(c) and (d), and 12-41-109(1)(b) and (c), C.R.S.
[30] §§ 12-41-107(1)(a) and 12-41-111(1)(a), C.R.S.
[31] §§ 12-41-107(1)(b) and 12-41-111(1)(c), C.R.S.

Examination applicants who received their education and training outside of the United States must also submit evidence that they possess an active, valid PT license (or other authorization to practice physical therapy) in the country where the applicant is practicing or has practiced.[32]

Applicants for licensure by endorsement must possess an active license in good standing from another U.S. state or territory, and have done one of the following:[33]

- Graduated from an accredited physical therapy education program within the past two years and passed an examination substantially equivalent to Colorado's;
- Passed an examination substantially equivalent to Colorado's and demonstrated their continued competence either by completing an internship or by another method as established in rule; or
- Practiced as a licensed PT for at least two of the past five years.

The Director may deny a license to any applicant who has violated the Act.[34]

PTs must renew their licenses every two years by submitting a renewal application and paying a required fee.[35]

Individuals meeting certain defined criteria are exempt from the Act. For example, students enrolled in an accredited physical therapy program may practice physical therapy, provided they are under the direction and immediate supervision of a Colorado-licensed PT. PTs licensed in other states who are in Colorado for an educational program, such as a fellowship or internship, may practice for up to six weeks without a Colorado license. A PT from another state or country may care for a particular patient who is in Colorado temporarily, but the PT cannot provide physical therapy services for any other individuals and cannot represent himself or herself as a Colorado-licensed PT.

Use of Unlicensed Personnel

PTs may use unlicensed personnel in their practices. Such personnel include physical therapy aides, physical therapy students, and physical therapist assistants (PTAs). PTs may supervise no more than three such unlicensed individuals at one time.[36]

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[32] § 12-41-111(1)(b), C.R.S.
[33] § 12-41-109(3), C.R.S.
[34] §§ 12-41-107(3), 12-41-109(5), and 12-41-111(3), C.R.S.
[35] § 12-41-112(3), C.R.S.
[36] §12-41-113(1), C.R.S., and Colorado Physical Therapy Licensure Rules and Regulations, 4 CCR 732-1, 1C.

Although Colorado does not regulate PTAs, the Act defines a PTA as someone who:[37]

- Has successfully completed an accredited PTA program;
- Is registered, licensed, or certified as a PTA in another state; or
- Has otherwise qualified to take the physical therapy examination.

PTAs must practice under the responsible direction and supervision of a PT.[38] By rule, "responsible direction and supervision" means that the supervising PT is accountable for all acts delegated to the PTA.[39]

Unlicensed personnel who do not fall under the definition of PTA are considered physical therapy aides.[40] PTs must directly supervise physical therapy aides, meaning they must be on the premises and in the same building when an unlicensed person is performing a delegated task.[41]

The rules of the Director prohibit PTs from delegating certain duties to unlicensed personnel, namely:[42]

- Interpretation of referrals from physicians and other healthcare providers;
- Initial examinations and evaluations;
- Diagnosis and prognosis;
- Development and modification of plans of care;
- Determination of discharge criteria;
- Supervision of all care rendered to the patient/client; and
- Sharp, enzymatic, selective, and pharmacological wound debridement.[43]

The supervising PT bears responsibility for all delegated tasks performed by unlicensed individuals and is legally accountable for the care they provide.[44]

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[37] §12-41-113(1), C.R.S.
[38] §12-41-113(1), C.R.S.
[39] Colorado Physical Therapy Licensure Rules and Regulations, 4 CCR 732-1, 2D.
[40] Colorado Physical Therapy Licensure Rules and Regulations, 4 CCR 732-1, 3A.
[41] §12-41-113(1), C.R.S. and Colorado Physical Therapy Licensure Rules and Regulations, 4 CCR 732-1, 3D.
[42] Colorado Physical Therapy Licensure Rules and Regulations, 4 CCR 732-1, 1D and E.
[43] PTAs—but not physical therapy aides or students—may perform soft or non-selective wound debridement, per Colorado Physical Therapy Licensure Rule 1E.
[44] Colorado Physical Therapy Licensure Rules and Regulations, 4 CCR 732-1, 2A, 2C, 3A, 3B, and 3F.

Complaints and Enforcement

One of the Director's critical responsibilities under the Act is to investigate complaints against PTs, and take disciplinary action against PTs who violate the Act. PTs may be subject to discipline if they are found to have:[45]

- Committed any act which does not meet generally accepted standards of physical therapy practice or failed to perform an act necessary to meet generally accepted standards of physical therapy practice;
- Engaged in a sexual act with a patient while a patient-PT relationship exists;
- Failed to refer a patient to the appropriate healthcare practitioner when the patient needs services that are beyond the level of competence of the PT or beyond the scope of physical therapy practice;
- Abandoned a patient by any means;
- Failed to provide adequate or proper supervision of unlicensed personnel;
- Failed to make essential entries on patient records or falsified or made incorrect entries of an essential nature on patient records;
- Ordered or performed tests or treatments that are either demonstrably unnecessary or contrary to recognized standards of physical therapy practice;
- Committed abuse of health insurance or a fraudulent insurance act;
- Offered, given, or received commissions, rebates, or other forms of remuneration for the referral of clients;
- Falsified information in any application or attempted to obtain or obtained a license by fraud, deception, or misrepresentation;
- Engaged in the habitual or excessive use of any habit-forming drug or has a dependence on or addiction to alcohol or any habit-forming drug;
- A physical or mental condition or disability which renders them unable to treat patients with reasonable skill and safety;
- Failed to notify the Director, in writing, of the entry of a final judgment for malpractice or any settlement in response to charges or allegations of malpractice of physical therapy;
- Been convicted of a felony or pled guilty or *nolo contendere* to a felony; or
- Advertised, represented, or held themselves out as PTs or practiced physical therapy without a license.

If an investigation reveals that a PT has violated the Act, the Director may take formal disciplinary action. Possible actions include suspending or revoking the PT's license, imposing a fine of up to $1,000, or placing the PT on probation.[46] In any disciplinary action that allows a PT to continue to practice, the Director may place conditions on the PT, such as requiring the PT to undergo therapy, complete additional education, or complete a period of supervised practice. The Director may also place specific restrictions on a PT's scope of practice to ensure that the PT does not go beyond his or her level of competence.[47]

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[45] § 12-41-115, C.R.S.
[46] §§ 12-41-116(1)(a), and 122(2), C.R.S.
[47] § 12-41-116(3), C.R.S.

If the Director has reason to believe that a PT poses an imminent threat to the public health and safety, or if a person is practicing physical therapy without a license, the Director can issue an order to cease and desist such activity.[48]

The Director may order a PT to undergo a physical or mental examination to determine whether the PT is able to practice with reasonable skill and safety.[49]

If the Director determines that the violation does not warrant formal disciplinary action, but is still too significant to be dismissed, the Director may issue a letter of admonition.[50]

If the Director finds that a PT's conduct does not warrant formal action, the Director dismisses the complaint. However, if the complaint reveals behavior on the part of the PT that, if repeated, might lead to serious consequences, the Director has the option of dismissing the complaint via a confidential letter of concern.[51]

Corporate Practice

The Act permits PTs to form professional service corporations for the practice of physical therapy.[52] The corporation's president and all shareholders must be Colorado-licensed PTs. The Act forbids directors and officers who are not PTs from exercising any authority over professional matters.[53] Employment of PTs in specified settings, including hospitals, nursing or rehabilitation facilities, and educational entities are not considered the corporate practice of physical therapy as long as:[54]

- The PT's ability to exercise independent judgment is unaffected;
- The PT is not required to exclusively refer any patient to a particular provider or supplier or take any other action he or she determines not to be in the patient's best interest; and
- The policies of the employing entity include a procedure for hearing and resolving complaints alleging that any of the above provisions have been violated.

Pursuant to section 6-18-303(2), C.R.S., a PT may work in a physician-owned physical therapy clinic only if such clinic takes specific measures to safeguard the PT's ability to exercise independent judgment.

[48] § 12-41-117(11)(a), C.R.S.
[49] § 12-41-118(1), C.R.S.
[50] § 12-41-116(2)(a), C.R.S.
[51] § 12-41-116(3.5), C.R.S.
[52] § 12-41-144(1), C.R.S.
[53] §§ 12-41-144(1)(d) and (f), C.R.S.
[54] § 12-41-144(5)(b), C.R.S.

Program Description and Administration

The Director of the Division of Registrations (Director and Division, respectively) within the Colorado Department of Regulatory Agencies (DORA) is vested with the authority to regulate physical therapists (PTs). By policy, the Director delegates specified powers and duties to the director of the Health Services section within the Division, and to the director of the Office of Physical Therapy Licensure (Office).[55]

The Director appoints an advisory committee to assist him or her. The seven-member Physical Therapist Advisory Committee (Committee) meets quarterly. At a typical meeting, the Committee considers policy issues and current topics of interest to the PT community, and reviews complaints against PTs.

Table 1 illustrates, for the five fiscal years indicated, the expenditures and staff associated with PT regulation.

Table 1
Agency Fiscal Information

Fiscal Year	Total Program Expenditure	FTE
04-05	$131,632	0.7
05-06	$127,289	0.7
06-07	$154,733	0.55
07-08	$188,513	0.75
08-09	$185,746	0.7

For fiscal year 09-10, there were 0.80 full-time equivalent employees (FTE) allocated to the Office, including:

- General Professional VII (Section Director) = 0.05 FTE: Promulgates rules, takes disciplinary actions, and oversees all regulatory functions mandated in the Physical Therapy Practice Act (Act).
- General Professional VI (Program Director) = 0.10 FTE: Administers the day-to-day operations of the Office.
- Technician IV (Program Assistant) = 0.15 FTE: Processes complaints and disciplinary actions.
- Administrative Assistant III = 0.50 FTE: Provides general administrative support to the Office.

This number does not include employees in the centralized offices of the Division, which provide licensing, administrative, technical, and investigative support to the Office. However, the cost of those employees is reflected in the Total Program Expenditures. The slight fluctuations in the number of FTE from fiscal year 06-07 to 07-08 are due to administrative restructuring that occurred during that period.

[55] Office of Physical Therapy Licensure Policy 10-2.

Increased spending on legal services due to an unusually complex case explains the considerable increase in program expenditures from fiscal year 05-06 to 07-08.

Table 2 shows the fees associated with PT regulation for fiscal year 08-09.

Table 2
Office of Physical Therapy Licensure Fees
FY 08-09

Original License by Examination	$50
Original License by Endorsement	$50
Renewal	$70
Late Fee (for renewals submitted after the expiration date)	$15
Reinstatement	$85
Duplicate License	$5

Pursuant to section 24-34-105, Colorado Revised Statutes (C.R.S.), fees are subject to change every July 1.

Licensing

There are two primary routes to PT licensure in Colorado: by examination and by endorsement. Applicants must complete the appropriate application and submit it with all supporting documentation to the Division's Office of Licensing. A licensing specialist reviews the application and notifies the applicant of any deficiencies. Once the application is complete, a licensing specialist evaluates the application to ensure the applicant meets the requirements. If requirements are met, the license is issued. If not, the licensing specialist notifies the applicant in writing, and the application is kept on file for one year.

Table 3 illustrates, for the five fiscal years indicated, the number of new licenses issued by method.

Table 3
New PT Licenses Issued by Method

Fiscal Year	Licensed by Examination	Licensed by Endorsement
04-05	121	200
05-06	138	209
06-07	124	232
07-08	149	252
08-09	147	231

Although the number of new licenses has varied somewhat from year to year, the overall data show general growth in the PT profession over the five-year period. There are fewer new licenses issued by examination than by endorsement because the number of accredited physical therapy education programs nationwide is relatively low. This means the number of new graduates seeking to take the examination is also low.

Table 4 illustrates the total number of licensed PTs for the five fiscal years indicated.

Table 4
Total Number of Licensed PTs

Fiscal Year	Total
04-05	4,972
05-06	5,356
06-07	5,237
07-08	5,689
08-09	5,537

Again, although the number of licensed PTs has fluctuated from year to year, the overall pattern from fiscal year 04-05 to 08-09 demonstrates steady growth in the PT profession.

Examinations

To qualify for PT licensure, candidates must pass the National Physical Therapy Examination (NPTE), which was developed by the Federation of State Boards of Physical Therapy (FSBPT). The NPTE is intended to determine whether candidates have the knowledge and skills required of entry-level PTs. The examination focuses on the clinical application of knowledge, concepts and principles necessary to provide safe and effective patient care.[56]

The NPTE has 200 questions that cover four broad content areas.

[56] *2010 NPTE Candidate Handbook,* Federation of State Boards of Physical Therapy (2010), p. 20.

Table 5 indicates the content areas covered by the NPTE and the number of questions in each area.

Table 5
Content Areas for the National Physical Therapy Examination (NPTE)[57]

Content Area Description	Number of Questions	Percent of Questions
Clinical Application of Foundational Sciences	29	14.5
Examination/ Foundations for Evaluation, Differential Diagnosis, & Prognosis	73	36.5
Interventions/ Equipment & Devices; Therapeutic Modalities	59	29.5
Safety, Protection, & Professional Roles; Teaching & Learning; Research & Evidence-Based Practice	39	19.5
Total	200	100

Prometric provides computer-based testing services for the NPTE, offering the examination at approximately 300 testing locations nationwide[58] including four in Colorado, which are located in Colorado Springs, Grand Junction, Greenwood Village, and Longmont. Prometric charges candidates an examination fee of $70.60.[59]

Table 6 illustrates the number of PT examinations administered to Colorado PT applicants for the five fiscal years indicated, and the respective pass rates. The national average pass rates compiled by the FSBPT are provided for comparison.

Table 6
Number of Colorado Candidates Taking the NPTE and Pass Rates

Fiscal Year	Number of Examinations Given*	Colorado Pass Rate (%)	National Pass Rate (%)
04-05	195	65.6	75
05-06	195	65.6	78
06-07	173	75.7	74
07-08	216	72.7	74
08-09	193	76.2	77

* Includes first-time test takers only.

The pass rate for Colorado examinees has improved over the past five years, and now hovers near the national pass rate. Division staff had no specific explanation for the considerable improvement in the pass rate from fiscal year 05-06 to 06-07.

[57] *2010 NPTE Candidate Handbook,* Federation of State Boards of Physical Therapy (2010), p. 20.
[58] *2010 NPTE Candidate Handbook,* Federation of State Boards of Physical Therapy (2010), p. 8.
[59] *2010 NPTE Candidate Handbook,* Federation of State Boards of Physical Therapy (2010), p. 10.

Complaints/Disciplinary Actions

Anyone, including consumers, employers, insurance companies, and the Director, can file a complaint against a licensed PT or anyone who may have violated the Act.

Operating under the authority delegated by the Director, Office staff reviews incoming complaints to determine whether they might constitute a violation of the Act. If so, Office staff notifies the PT being complained against of the complaint and allows the PT 30 days to respond to the allegations. When the response is received, staff forwards the complaint and the response, as well as a preliminary recommendation for how the case should be handled, to the Director. Staff might recommend dismissing the case, forwarding the complaint to the Division's Office of Investigations, or forwarding the case to the Committee.

Table 7 illustrates the number and types of complaints received by the Office for the five fiscal years indicated.

Table 7
Complaints Filed against PTs

Nature of Complaints	FY 04-05	FY 05-06	FY 06-07	FY 07-08	FY 08-09
Practicing without a License	0	1	0	4	6
Standard of Practice	6	6	6	10	13
Scope of Practice	0	0	0	0	1
Sexual Misconduct	1	2	1	1	1
Patient Abandonment	0	0	1	3	2
Substance Abuse	0	1	0	0	0
Insurance Fraud	2	2	3	3	1
Failure to Make Essential Entries	1	0	1	0	1
Supervision of Physical Therapist Assistants	0	0	3	0	3
Failed to Notify Director of Criminal Convictions or Disciplinary Actions in Other Jurisdictions	0	0	0	0	2
Falsified Information	0	0	1	2	1
TOTAL	10	12	16	23	31

Office staff attributes the increasing number of substandard practice complaints to increasingly sophisticated healthcare consumers who are aware of their rights and know what avenues to take if they are not satisfied with the care they receive.

Table 8 illustrates the number and types of final actions taken by the Director for the five fiscal years indicated.

Table 8
Final Actions against PTs

Type of Action	FY 04-05	FY 05-06	FY 06-07	FY 07-08	FY 08-09
Revocation / Surrender / Voluntary Relinquishment	0	0	0	4	1
Suspension	1	0	1	1	3
Probation / Practice Limitation	3	1	3	3	6
Letter of Admonition	2	2	2	2	0
Injunctions	1	0	1	0	0
Total Disciplinary Actions	**7**	**3**	**7**	**6**	**10**
Dismissals	28	7	27	13	13
Dismissals with letters of concern	1	0	2	2	6
Total Dismissals	**29**	**7**	**29**	**15**	**19**

The spike in the number of dismissals in fiscal years 04-05 and 06-07 correlates with the attestation that PTs must complete during each renewal period. When renewing, PTs must attest that they are in compliance with the Act. This triggers PTs who have not been in compliance to disclose to the Office any criminal convictions, malpractice settlements, or other actions that might violate the Act. During the two renewal periods reflected in the table above—fiscal year 04-05 and 06-07—the Office opened a new complaint for each disclosure. In most cases, further investigation was not required, and the cases were dismissed. Since then, the Office has discontinued the practice of automatically opening complaints based on self-disclosures. Instead, the Office reviews the supporting documentation for each self-disclosure and determines on a case-by-case basis whether it merits opening a complaint.

Although the Director has the statutory authority to issue fines, no fines have been imposed for the past five years.

Because a complaint might be received in one fiscal year and resolved the next, the total number of disciplinary actions and dismissals for a given year might not match the total number of complaints for that year as reflected in Table 7.

Analysis and Recommendations

Recommendation 1 – Continue the regulation of physical therapists for seven years, until 2018.

Article 41 of Title 12, Colorado Revised Statutes (C.R.S.), known as the "Colorado Physical Therapy Practice Act" (Act), vests the power to regulate physical therapists (PTs) with the Director of the Division of Registrations (Director and Division, respectively) within the Department of Regulatory Agencies (DORA). The law authorizes the Director to license qualified applicants, promulgate rules, and discipline PTs found to have violated the Act.

The first sunset criterion asks whether this regulation protects the public health, safety and welfare.

In June 2010, there were 6,001 licensed PTs in Colorado.

PTs, like other health professionals, must be able to assess patients' health status, develop treatment plans, educate patients and their families, and evaluate and document patients' progress. However, at its core, physical therapy involves touching people who are injured, fragile, or in pain. This means that the potential for harm to the public is significant. Whether treating an athlete recovering from an injury or a person with multiple sclerosis learning to improve balance, PTs must possess considerable knowledge of anatomy and physiology, as well as the manual skills to treat patients safely and effectively. Colorado's licensure program ensures that PTs have this knowledge and these skills by requiring prospective PTs to meet specific minimum requirements, including completing an accredited education program and passing a comprehensive examination.

The Director has also established, in rule, minimum requirements for PTs wishing to perform treatments, such as dry-needling, that are not typically taught as part of a basic physical therapy education program. These additional requirements assure that PTs are qualified to perform the treatment safely.

The Act and the corresponding rules also protect the public by establishing standards for PT supervision of unlicensed personnel. Although the Act does not regulate physical therapist assistants (PTAs) *per se*, it defines PTAs as individuals meeting certain requirements, thereby restricting whom PTs may utilize as PTAs. The PT is responsible for the practice of the PTA, and his or her license depends on the appropriate direction, training, and supervision of the PTA.

Under section 12-41-115(1)(e), C.R.S., a PT may be subject to disciplinary action for failing to provide adequate or proper supervision of unlicensed personnel. With unregulated professions, there is sometimes a problem where the public does not have a place to lodge complaints against practitioners. In this case, however, because the PT has ultimate responsibility for the PTA's practice, consumers may lodge complaints with the Director. Based on the low number of complaints filed against PTs based on improper supervision of PTAs (a total of six complaints in five years), it is reasonable to conclude that this system has worked well for Colorado consumers, and meets the standard established in the second sunset criterion as the "least restrictive regulation consistent with the public interest."

The Director also protects the public by disciplining PTs who have violated the Act. The Director has numerous enforcement tools at his or her disposal: if a PT has a practice issue that could be corrected with further education or supervision, the Director may put the PT on probation. If a PT has caused significant harm to a patient, the Director may revoke that PT's license.

Through its licensing, rulemaking and disciplinary activities, the PT licensure program protects the public health, safety and welfare of Coloradans. For these reasons, the General Assembly should continue the regulation of PTs for seven years, until 2018. A seven-year sunset date appropriately reflects the scope of the changes this report recommends.

Recommendation 2 – Re-establish the Board of Physical Therapy and repeal the Physical Therapy Advisory Committee.

Having established that regulation is necessary to protect the public, the first sunset criterion also compels DORA to consider:

> ... whether the conditions which led to the initial regulation have changed; and whether other conditions have arisen which would warrant more, less or the same degree of regulation.

PT licensure was established in 1959 under the authority of a Board of Physical Therapy (Board). In 1985, the General Assembly, following a sunset recommendation, sunset the Board and instituted a "director model" program for PTs under the authority of the Director. Over the past 25 years, the profession of physical therapy has undergone significant changes. These changes warrant the re-establishment of the Board.

First, consider the context of the 1985 sunset recommendation. The full recommendation reads:

> The General Assembly should consider terminating the State Board of Physical Therapy and licensure for physical therapists.[60]

Why was abolishing not only the Board but the entire regulatory program a viable option in 1985? There were two main reasons.

At that time, there were numerous constraints on the independent practice of PTs. Colorado patients could not seek the services of a PT without a referral from a physician, podiatrist, or dentist. In fact, only five states allowed PTs this level of independence. At that time, PTs could also practice under the Medical Practice Act as physician extenders, thereby calling into question the need for a separate practice act.

Secondly, there was little evidence that the practice of physical therapy posed harm to the public. According to the report, most complaints submitted to the Board alleged misuse of the term "physical therapy" in advertising materials, rather than actual instances of physical harm to the public. Moreover, although by 1985 the Board had been in existence for over 25 years, it had never disciplined a single licensee, implying that either the Board was ineffective or the regulation unneeded.[61]

However, there have been significant changes since 1985, and even since the 2000 sunset review, which recommended keeping the Director model program in place. These changes justify a return to the Board model.

The first important change occurred in 1988, when Colorado implemented "direct access" to PTs. Direct access permitted PTs to practice independently, and firmly established that PTs themselves, not the prescribing or supervising physician, dentist or podiatrist, are accountable for their own practices. Since then, PT practice has become increasingly independent. Across the healthcare spectrum, there is a general trend toward greater use of mid-level health care providers, such as PTs.

The second significant change that has occurred since the last sunset review is in the level of education of the average PT. In 1999, there were 199 accredited physical therapy programs: 24 offering bachelor's degrees, 157 offering master's degrees, and 8 offering doctoral degrees. In 2009, there were 212 physical therapist education programs: 12 offering master's degrees and 200 offering doctoral degrees. There are no longer any accredited physical therapy programs that offer bachelor's degrees.

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[60] *Sunset Review: State Board of Physical Therapy*, Colorado Department of Regulatory Agencies (July 1985), p. 8.
[61] *Sunset Review: State Board of Physical Therapy*, Colorado Department of Regulatory Agencies (July 1985), p. 8.

This dramatic increase in basic PT education represents how the rapid pace of scientific and technological advancements has affected the profession of physical therapy. For example, medical technology that allows increasingly sophisticated orthopedic surgeries, and scientific research that changes our understanding of how neurological disorders affect the brain, necessitate changes to the way PTs treat patients. Physical therapy education programs have evolved and expanded accordingly. An increasingly complex healthcare environment means that an entry-level PT in 2010 must possess a greater body of knowledge, skills and abilities than an entry-level PT in 2000.

These increased levels of independence and complexity have led to more practice questions—relating to, for example, PT scope of practice, and appropriate supervision—than there have been in the past. The Director does not have the specific professional expertise to address these matters without assistance. Consequently, although the Director possesses formal rulemaking authority for the PT program, the Committee plays a significant and critical role in rulemaking and policy-setting.

Finally, the number of substandard practice complaints has risen steadily. From 1995 to 2000, the Director reviewed 74 complaints, 24 percent of which alleged substandard practice. From fiscal year 04-05 to 08-09, the Director reviewed a total of 92 complaints, 41 of which—44 percent—related to substandard practice. A representative of DORA reviewed all complaints against PTs received during fiscal years 07-08 and 08-09. Of 48 cases, 18 could not be evaluated without professional expertise.

This shift has led the Director to refer more complaints to the Committee, and to rely on its expertise in this area, as well.

In essence, although the Director is ultimately the regulatory authority, the Committee has been functioning more and more as a board.

Division staff does not anticipate that returning to a Board model will be significantly more expensive than the current Director model program. Committee members already meet quarterly, receive a per diem, and are reimbursed for their expenses, and there is no indication that a Board model would require significantly more staff time and resources than are currently used in working with the Committee.

The practice of physical therapy has become increasingly independent and complex, resulting in more substandard practice complaints and practice issues requiring professional expertise. By advising the Director and providing this expertise, the Committee has essentially been acting as a Board. For these reasons, the General Assembly should re-establish the Board.

Over the course of this sunset review, DORA identified numerous developing issues in the PT profession the Board should address.

Telehealth. Telehealth is the use of telecommunication technology—including interactive audio, video, and data communications—to provide healthcare services, educate the public about health-related issues, and facilitate medical research across distances.[62] For example, a rural clinic that might not have the resources to employ a PT on-site could hire a PT from another area of the state to treat patients via telehealth. This could involve the PT using interactive video to demonstrate a therapeutic exercise program to patients, and to observe patients performing the exercises to assure they are being done correctly.

Telehealth could potentially increase access to physical therapy services, particularly to people in underserved or rural areas.

However, the practice of telehealth presents a challenge to regulators. What is the standard of care for physical therapy provided via telehealth? How can Colorado adequately protect the health and safety of its citizens, without unnecessarily restricting access to physical therapy services?

The Board would have the professional expertise to explore this issue and establish parameters for this growing area of healthcare.

Supervision of unlicensed personnel. DORA identified two issues relating to the supervision of unlicensed personnel.

The first issue is the statutory cap on the number of unlicensed personnel a PT may supervise.

Currently, under section 12-41-113(1), C.R.S., PTs may supervise no more than three unlicensed personnel. That number may include PTAs, physical therapy aides, and physical therapy students.

It is not uncommon for the law to limit the number of assistants a health professional may supervise. For example, physicians may supervise no more than four physician assistants, and chiropractors may supervise no more than five chiropractic assistants. However, among the health professions, there is no other instance where the law limits the number of aides or students a healthcare provider may supervise. These decisions are left to employers and healthcare providers themselves.

Ultimately, PTs are responsible for the care provided by unlicensed personnel acting under their supervision. It is in PTs' best interest to assure that they do not assume more supervisory responsibility than they can safely handle.

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[62] The Free Dictionary. *Telehealth.* Retrieved on September 20, 2010, from http://medical-dictionary.thefreedictionary.com/telehealth

Increasing the number of personnel a PT may supervise, or removing the cap entirely, could potentially increase access to healthcare services by allowing PTs to include more unlicensed personnel in their practices.

The Board would have the professional expertise to determine whether the cap is justified, and if so, whether the ratio established by law is reasonable.

The second issue relates to the appropriate levels of supervision for PTAs, and for other unlicensed personnel.

Section 12-41-113(1), C.R.S., establishes two tiers of supervision for unlicensed personnel:

> (Unlicensed) individuals shall at all times be under the **direct supervision** of the physical therapist unless such individuals are physical therapist assistants who shall be under **responsible direction and supervision** of the physical therapist. {emphasis added}

"Direct supervision" is subsequently defined as supervision that occurs on the premises where any such unlicensed individuals are practicing.[63] Rule 3C, within the Colorado Physical Therapy Licensure Rules and Regulations, clarifies this definition to mean supervision that is on the premises and in the same building where any such unlicensed personnel are practicing.

"Responsible direction and supervision" is defined only in rule. Rule 2D defines it as:[64]

> ...direction and supervision provided by a physical therapist that assumes accountability for the delegated acts of the unlicensed person identified as a physical therapist assistant.

But Rule 3F establishes that PTs are equally accountable for the delegated acts of the unlicensed person defined as a physical therapy aide. This definition of "responsible direction and supervision" does not provide meaningful differentiation between the two types of supervision.

Since PTs can be subject to disciplinary action for improper supervision of unlicensed personnel, it is important that PTs' supervisory obligations are clear.

The Board would have the professional knowledge to clarify the dual supervisory role of the PT, and any other issues regarding delegation or the supervision of licensed or unlicensed personnel.

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[63] § 12-41-113(1), C.R.S.
[64] Colorado Physical Therapy Licensure Rules and Regulations, 4 CCR 732-1, Rule 2D.

Approval of dry-needling education programs. Currently, PTs wishing to perform the dry-needling technique may do so by meeting the educational requirements set forth in the Director's Rule 11. However, there is no system in place for the review and approval of dry-needling education courses. This means that an education program could include training that is considerably beyond the scope of the Director's narrow definition of what constitutes dry-needling.

Because the practice of dry-needling could pose potentially significant harm—to cite an extreme example, an improperly placed needle could puncture a patient's lung—there should be an approval process for entities wishing to offer the training in this procedure. The Board would have the professional expertise to develop and implement such a review and approval process.

The new Board should include seven Governor-appointed members: four licensed PTs, and three members of the public who are not licensed PTs and who do not have a direct or indirect financial interest in the practice of physical therapy. Whenever possible, the Governor should appoint members representing diverse geographic areas. In keeping with other healthcare boards, Board members should serve four-year terms, and should be able to serve no more than two consecutive terms.

The implementation date of the Board should be January 1, 2012, which will give the Governor sufficient time to appoint Board members. A January 1, 2012 implementation date also provides ample time for Division staff to transition from a Director model to formal board oversight.

In light of this change, the General Assembly should repeal the Committee created in section 12-41-126, C.R.S.

Recommendation 3 – Permit PTs to use automated external defibrillators.

Automated external defibrillators (AEDs) are computerized medical devices that can evaluate the rhythm of a person's heart and advise rescuers when a shock is needed.[65] AEDs—which are widely available in high-traffic areas such as airports, shopping malls, and office buildings—were designed for use by ordinary citizens rather than medical personnel.

[65] American Heart Association. *AED Programs Q&A.* Retrieved on September 20, 2010, from http://www.americanheart.org/presenter.jhtml?identifier=3011859

Under Colorado's Good Samaritan Law, any person is permitted to provide emergency care at the scene of an emergency or accident, as long as such care is performed in good faith and at no cost.[66] Section 12-41-105(1)(b), C.R.S., however, specifically prohibits PTs from using potentially lifesaving devices such as AEDs. This prohibition creates a scenario where a layperson with no healthcare training whatsoever is permitted to use an AED, but a licensed PT is forbidden from doing so. While the intent of the legislation creating the prohibition is unknown, it seems odd that a licensed PT who intervenes in an emergency, perhaps even saving a person's life, might be faced with discipline for doing so.

In the interest of the public health, safety, and welfare, this prohibition should be lifted.

Recommendation 4 – Add the Program of All-inclusive Care for the Elderly (PACE) to the list of PT work settings that are exempt from the corporate practice law.

Section 12-41-124(5)(b), C.R.S., exempts certain work settings from the provisions regulating corporate practice. These settings include licensed or certified hospitals, skilled nursing facilities, home health agencies, hospices, comprehensive outpatient rehabilitation facilities, accredited educational entities, and other entities "wholly owned and operated by the government."

The Program of All-inclusive Care for the Elderly (PACE) is a program for older adults and people over age 55 living with disabilities. PACE is intended to allow individuals who need the level of care typically provided in a nursing home to continue to live in their homes and communities. Individuals may pay for PACE services on their own, or, if they qualify, Medicare and Medicaid will pay for services. The PACE model offers a wide variety of services, including physical therapy.

A non-profit organization runs Colorado's PACE program, meaning that although the program receives public funding, it is not operated by the government. This means that the PACE program would not be able to employ PTs without being subject to the corporate practice provisions.

Generally speaking, the purpose of the regulation of corporate practice by healthcare providers, including PTs, is to assure that healthcare practitioners remain accountable to their patients rather than to shareholders. It is reasonable to assume that the General Assembly did not intend for the corporate practice provisions to apply to a program that receives government funding and is operated by a non-profit entity. Therefore, the General Assembly should add PACE to the list of PT work settings that may be exempted from the corporate practice law.

[66] § 13-21-108(1), C.R.S.

Recommendation 5 – Establish that a PT's failure to properly address his or her own physical or mental condition is grounds for discipline, and authorize the Board created in Recommendation 2 to enter into confidential agreements with PTs to address their respective conditions.

One of the Director's critical responsibilities is to take disciplinary action against PTs who pose a threat to the patients under their care. The Director may take disciplinary action against any PT who has:[67]

> A physical or mental condition or disability which renders such licensee unable to treat patients with reasonable skill and safety or which may endanger the health or safety of persons under the licensee's care.

Having such a condition may affect an applicant's ability to be licensed as a PT. The application for initial licensure asks:[68]

> Within the last five years, have you been diagnosed or treated for any physical or mental condition or disability which rendered you unable to treat patients with reasonable skill and safety or which may endanger the health or safety of persons under your care?

Further, at each two-year renewal, PTs must attest that they are in compliance with the Act, so in effect they are attesting that they do not have such a physical or mental condition. If they have acquired such a condition since the last renewal, they must disclose such to the Director.

The intent of these provisions is clear: to protect the public from unsafe practitioners. But in many cases, PTs with such conditions could continue to practice safely, under certain defined circumstances. For example, a PT with a spinal injury could continue to diagnose and evaluate patients, but would have to delegate certain manual therapies to another practitioner. A PT with bipolar disorder might be able to treat patients safely provided he or she takes the proper medication.

Under the current system, PTs with such conditions may enter into an agreement or practice limitation with the Director in order to continue practicing via a public disciplinary order. Section 12-41-116(3), C.R.S., states that:

> In any disciplinary order which allows a physical therapist to continue to practice, the Director may impose upon the licensee such conditions as the Director deems appropriate to ensure that the physical therapist is physically, mentally, and professionally qualified to practice physical therapy in accordance with generally accepted professional standards.

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[67] § 12-41-115(1)(m), C.R.S.
[68] Colorado Office of Physical Therapy Licensure, Application for Original License by Examination, May 2010, p. 2, question 2.

Such conditions may include requiring a PT to undergo a physical or mental examination; to complete therapy, training, or education; or to enter into a period of supervised practice. The Director may also restrict the scope of the PT's practice to ensure that the PT does not practice beyond the limits of his or her capabilities.[69]

These orders provide a mechanism for these PTs to continue to practice, but are troubling philosophically. The orders are considered discipline, and become part of the PT's permanent record. Being injured in a car accident, suffering a stroke, or receiving a diagnosis of bipolar disorder is fundamentally different from committing an act that constitutes grounds for discipline under the Act. While these conditions might temporarily or permanently affect a PT's ability to treat patients, it seems unjust for a PT who successfully manages bipolar disorder with medication to be included in the same category as a PT who has stolen a car or committed insurance fraud. Not only does this stigmatize the person with the condition, it can affect his or her ability to participate in provider networks and can increase insurance rates.

Essentially, current law compels the Director to discipline PTs simply for having a physical or mental condition that might affect their practice.

During the 2010 legislative session, the General Assembly passed Senate Bill 10-1260 (SB 1260), which contains a provision allowing the Medical Board to enter into confidential agreements with physicians with physical or mental conditions that might affect their practice. These agreements establish the measures that physicians must adhere to in order to practice safely.

The legislation made another important change: previously, a physician would be subject to discipline simply for having a physical or mental condition that might affect his or her practice. Under SB 1260, the Medical Board may discipline a physician if he or she fails to:[70]

> Notify the board...of a physical or mental illness or condition that impacts the licensee's ability to perform a medical service with reasonable skill and with safety to patients, failing to act within the limitations created by a physical or mental illness or condition that renders the licensee unable to perform a service with reasonable skill and with safety to the patient, or failing to comply with the limitations agreed to under a confidential agreement (.)

[69] § 12-41-116(3), C.R.S.
[70] Senate Bill 10-1260, § 29.

Simply having a physical or mental condition or illness is no longer a reason to impose discipline. As long as the physician notifies the Medical Board of his or her condition or illness, enters into a confidential agreement outlining the measures he or she must take to assure safe practice, and adheres to the agreement, there is no violation of the Medical Practice Act. Consequently, these agreements do not constitute discipline and do not appear to be reportable to the National Practitioner Data Bank. If a physician fails to meet the requirements or stay within the limitations enumerated in the agreement, the Medical Board may then take disciplinary action. This assures adequate public protection.

The General Assembly should enact a similar provision for PTs by granting the Board created in Recommendation 2 the authority to enter into confidential agreements with PTs. To assure public protection, the General Assembly should also establish failure to properly address the PT's own physical or mental condition as grounds for discipline.

Recommendation 6 – Require PTs to maintain professional liability insurance.

Professional liability insurance provides a means by which consumers may be made financially whole in the event that they have to file a malpractice claim against a healthcare professional. Many healthcare providers, including chiropractors,[71] podiatrists,[72] optometrists,[73] dentists,[74] physicians,[75] and advanced practice nurses[76] are required to maintain such insurance coverage.

According to stakeholders interviewed over the course of this review, most—if not all—PTs already hold professional liability insurance; however, there is no requirement that they do so. This places the patients under their care at risk, in the event they have cause to pursue legal action.

Professional liability insurance is readily available for PTs. According to the Colorado chapter of the American Physical Therapy Association, PTs typically hold policies that provide coverage of at least $1 million per occurrence, and $3 million to $5 million aggregate per year. Average annual premiums for such policies are $450 to $500 for full-time PTs and $250 to $300 for part-time PTs.

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[71] § 12-33-116.5, C.R.S.
[72] § 12-32-102(2), C.R.S.
[73] § 12-40-126, C.R.S.
[74] § 13-64-301, C.R.S.
[75] § 13-64-301, C.R.S.
[76] § 12-38-111.8, C.R.S.

Because PTs practicing without professional liability insurance could place the public at risk, and because such insurance coverage appears to be available and reasonably priced, the General Assembly should require PTs to secure professional liability insurance. Based on current market standards, the General Assembly should require PTs to secure a policy that provides coverage of up to $1 million per occurrence, and up to $3 million aggregate per year.

In many professions, there are lesser financial responsibility requirements in place for practitioners meeting certain criteria, i.e., podiatrists who do not perform surgical procedures,[77] optometrists engaged primarily in non-clinical duties,[78] or physicians whose practice is confined to a federal or military agency.[79] The General Assembly should grant the Board created in Recommendation 2 the authority to promulgate rules establishing such lesser requirements as appropriate.

Recommendation 7 – Revise the language relating to drug and alcohol use.

The Director may take disciplinary action against a PT who has:

> A dependence on or addiction to alcohol or any habit-forming drug or abuses or engages in the habitual or excessive use of any such habit-forming drug or any controlled substance(.)[80]

This wording presents two problems. First, it can be difficult to prove conclusively that someone is addicted to or dependent on alcohol or drugs. Second, because addiction is now understood as an illness, disciplining someone for being addicted may have legal ramifications.[81]

The "excessive use or abuse of alcohol" has been established as the standard for disciplinary action in Colorado. This standard establishes the excessive use or abuse of alcohol or drugs as grounds for discipline, rather than the condition of being addicted to or dependent on such substances.

Therefore, the General Assembly should amend this provision to remove references to "addiction" and "dependence," and state "the habitual or excessive use or abuse of alcohol, controlled substances, or any habit-forming drug."

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[77] § 12-32-102(2)(b), C.R.S.
[78] § 12-40-126(2), C.R.S.
[79] Colorado State Board of Medical Examiners *Rule 220, Rules and Regulations Regarding Financial Responsibility Standards*, § 2a.
[80] §12-41-115(1)(l), C.R.S.
[81] The U.S. Supreme Court ruled in *Robinson v. California*, 370 U.S. 660 (1962), that addiction is an illness, which may be contracted innocently or involuntarily, and, therefore, the State of California could not punish a person based on such grounds.

Recommendation 8 – Require PTs who have had their licenses revoked, or who have surrendered their licenses in lieu of disciplinary action, to wait two years to reapply.

Most healthcare professionals who have had their licenses revoked, or who have surrendered their licenses in lieu of revocation, must wait two years to reapply for licensure. These professionals, including dentists, midwives, nurses, podiatrists, and pharmacists, are required to wait two years. Requiring individuals to wait a specified period before reapplying enhances public protection by assuring they possess minimal competency when they re-enter the workforce. Given the severity of the violations that result in revocation or surrender of a license, and the amount of time and resources it takes to process revocations and surrenders, two years is an appropriate waiting period.

The General Assembly should establish a two-year waiting period for PTs who have had their licenses revoked, or who have surrendered their licenses in lieu of disciplinary action.

Recommendation 9 – Establish failure to respond to a complaint as grounds for discipline.

When the Director receives a complaint against a PT, he or she sends a copy of the complaint to the licensee. The PT has 30 days to respond to the complaint in writing. It is critical that the PT respond promptly, because failing to respond to a complaint does not just create an administrative inconvenience and hinder the investigative process, it also poses a potential threat to the public: each day that an unsafe PT continues to work puts the public at risk. While there may be extenuating circumstances that prevent the PT from responding promptly, the Board created in Recommendation 2 should have the authority to discipline a PT for failing to respond.

Other health professionals—including physicians,[82] nurses,[83] and chiropractors,[84] are subject to discipline for failing to respond to a complaint.

Therefore, the General Assembly should establish as grounds for discipline failure to respond to a complaint.

[82] § 12-36-117(1)(gg), C.R.S.
[83] § 12-38-117(1)(u), C.R.S.
[84] § 12-33-117(1)(ff), C.R.S.

Recommendation 10 – Repeal the provision relating to denying renewal of an existing PT license.

Section 12-41-116(1)(b), C.R.S., states:

> The denial of an application to renew an existing license shall be treated in all respects as a revocation. If an application to renew a license is denied, the applicant, within sixty days after the date of the notice of such action, may request a hearing as provided in section 24-4-105, C.R.S.

This language does not reflect current Division practice. If a PT against whom there is a pending complaint submits a renewal application, standard Division practice is not to deny the renewal. Rather, the Director continues with the investigative and disciplinary process, including revocation proceedings, if applicable. This process of stripping unsafe PTs of their licenses offers the same degree of public protection as the one outlined in statute, without sacrificing PTs' right to due process. Therefore, this provision should be repealed.

Recommendation 11 – Make technical changes to the Act.

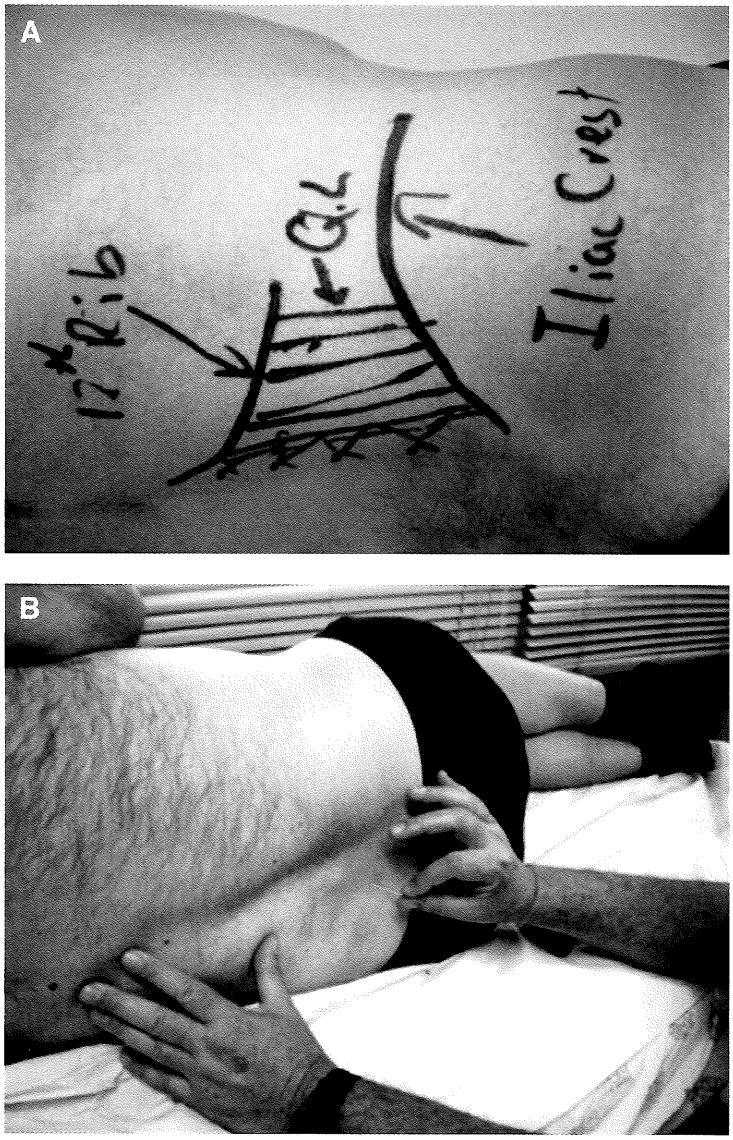
During the course of this sunset review, the Division, its staff and researchers found several places in the Act that need to be updated and clarified to reflect current practices, conventions, and technology. While recommendations of this nature generally do not rise to the level of protecting the health, safety, and welfare of the public, unambiguous laws make for more efficient implementation. Unfortunately, all of the statutes pertaining to PTs are commonly only examined by the General Assembly during a sunset review.

The following list of such technical changes is provided as a means of illustrating examples only. It is not exhaustive of the types of technical changes that should be made:

- Revise the entire Act to make it gender-neutral.
- Delete all statutory references to the Director developing or administering the examination, because the Federation of State Boards of Physical Therapy, not the Director, now develops the examination content, and a computer based testing vendor administers the examination.
- Sections 12-41-103(5) and 104, C.R.S. – Delete all references to "physical therapy technician," as that term is no longer commonly used.

Therefore, the General Assembly should make technical changes to the Act.

Figure 1. Examples of dry needling applications. A: Marking out the quadratus lumborum muscle before needling. B: Needling the paraspinal muscles.



mings and White,[10] in their systematic review of 23 RCTs of needling therapies (dry needling or injections), stated that direct needling of MTrPs seems to be an effective treatment, but the hypothesis that needling therapies have efficacy beyond placebo is neither supported nor refuted by the evidence from clinical trials. Any effect of these therapies is probably because of the needle or placebo rather than the injection of either saline or active drug.

The most recent systematic review included 7 RCTs of acupuncture and dry needling for the management of MTrPs.[24] Evidence from one study suggested that direct MTrP needling was effective in reducing pain compared with no intervention. Two studies provided contradictory results when comparing direct needling of MTrPs versus needling elsewhere in muscle; the evidence from another 4 studies failed to show that needling directly into an MTrP is superior to various nonpenetrating sham interventions. Tough and colleagues[24] mentioned significant methodological limitations of original studies included in the review. Firstly, although MTrPs seem to have been identified carefully in most studies, it is not clear that they were

Attachment 2

RULE 11 - REQUIREMENTS FOR PHYSICAL THERAPISTS TO PERFORM DRY NEEDLING

A. Dry needling (also known as Intramuscular Manual Therapy or Trigger Point Dry Needling) is a physical intervention that uses a filiform needle to stimulate trigger points, diagnose and treat neuromuscular pain and functional movement deficits, is based upon Western medical concepts, requires an examination and diagnosis, and treats specific anatomic entities selected according to physical signs. Dry needling does not include the stimulation of auricular or distal points.

B. Dry needling as defined pursuant to this rule is within the scope of practice of physical therapy.

C. A physical therapist must have the knowledge, skill, ability, and documented competency to perform an act that is within the physical therapist's scope of practice. Except as part of a course of study on dry needling pursuant to paragraph D.2 of this Rule, a physical therapist shall not perform dry needling unless competent to do so.

D. ~~To be deemed competent to perform dry needling, a physical therapist must meet the following requirements~~:

1. ~~Documented successful completion of a dry needling course of study. The course must meet the following requirements:~~

   a. ~~A minimum of 46 hours of face-to-face IMS/dry needling course study; online study is not considered appropriate training~~.

   b. ~~Two years of practice as a licensed physical therapist prior to using the dry needling technique.~~

To be deemed competent to perform dry needling, a physical therapist must:

1. have practiced for at least two years as a licensed physical therapist; and

~~1.~~2. have successfully completed a dry needling course of study that consists of a minimum of 46 hours of in-person (*i.e.* not online) dry needling training.

E. A provider of a dry needling course of study must meet the educational and clinical prerequisites as defined in this rule, paragraph D above~~D(1) (a) &(b)~~ and demonstrate a minimum of two years of dry needling practice techniques. The provider is not required to be a physical therapist.

F. A physical therapist performing dry needling in his/her practice must have written informed consent for each patient where this technique is used. The patient must sign and receive a copy of the informed consent form. The consent form must, at a minimum, clearly state the following information:

1. Risks and benefits of dry needling

2. Physical therapist's level of education and training in dry needling

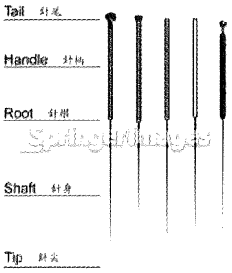
3. The physical therapist will not stimulate any distal or auricular points during dry needling.

G. When dry needling is performed, it must be clearly documented in the procedure notes and must indicate how the patient tolerated the technique as well as the outcome after the procedure.

H. Dry needling shall not be delegated and must be directly performed by a qualified, licensed physical therapist.

I. Dry needling must be performed in a manner consistent with generally accepted standards of practice, including clean needle techniques, and the guidelines and recommendations of the Centers for Disease Control and Prevention ("CDC").

J. The physical therapist ~~must be able to~~ shall supply written documentation, upon request by the Board, which substantiates appropriate training as required by this Rule. Failure to provide written documentation, upon request, is a violation of this rule, and is prima facie evidence that the physical therapist is not competent and not permitted to perform dry needling.



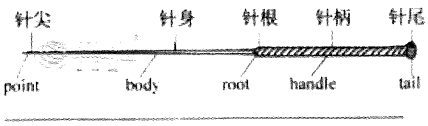
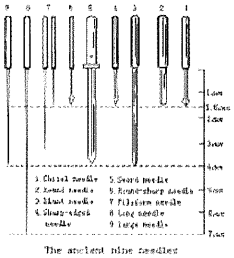
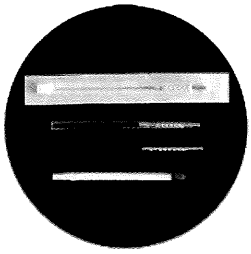
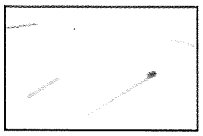
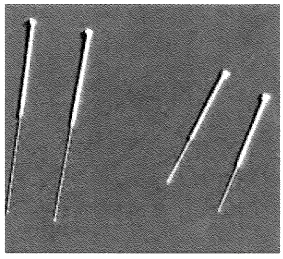


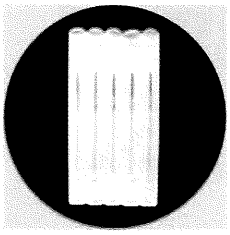
Fig. 1-1 Structure of the filiform needle











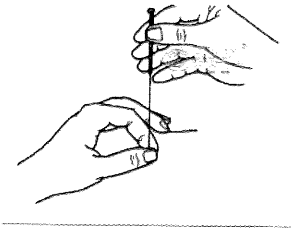
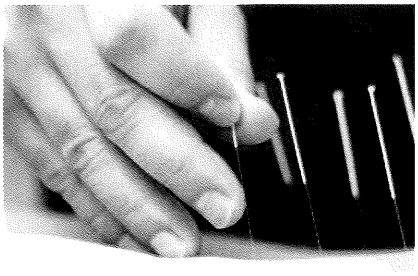
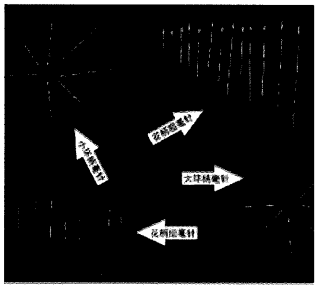


Fig. 1-8 Holding with double hands





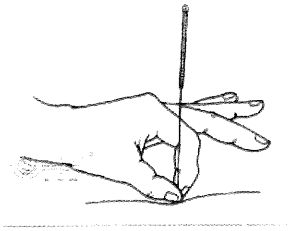
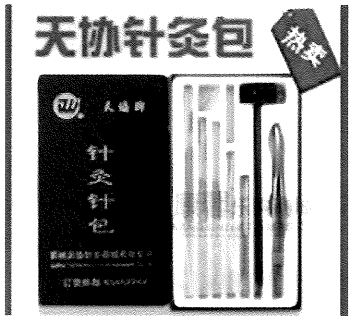
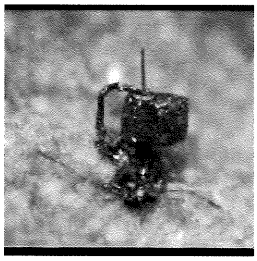
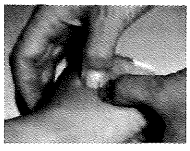
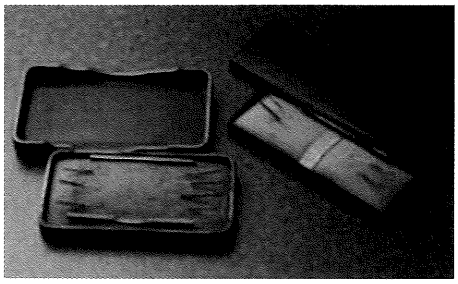


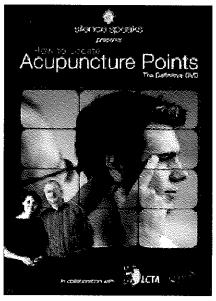
Fig. 1-24 Insertion by gripping the sharp part of the needle

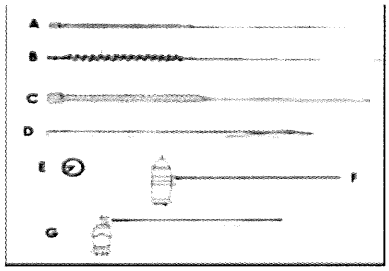


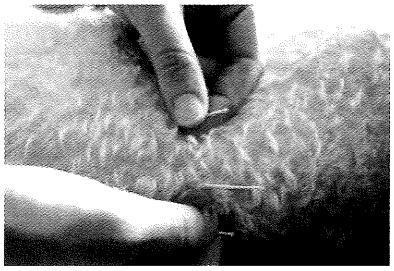












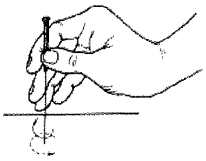
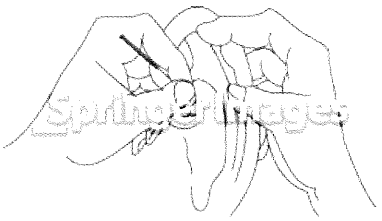
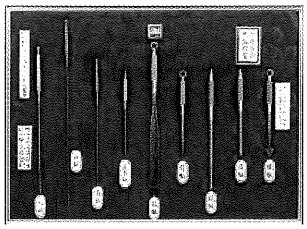
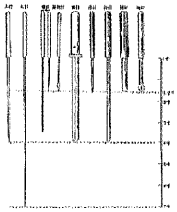
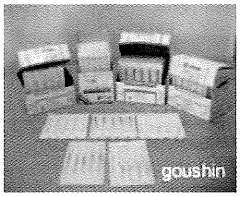


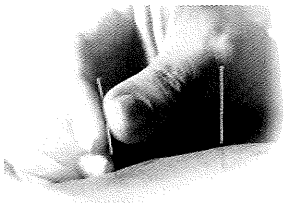
图 2 - 2 捻转法
Fig. 2 - 2 Rotating techniques

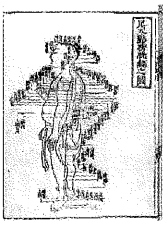




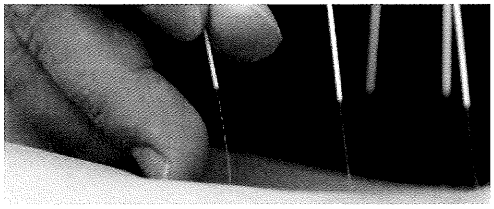


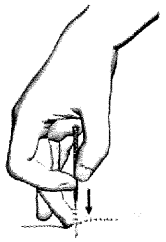






Acupuncture





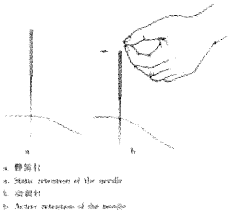
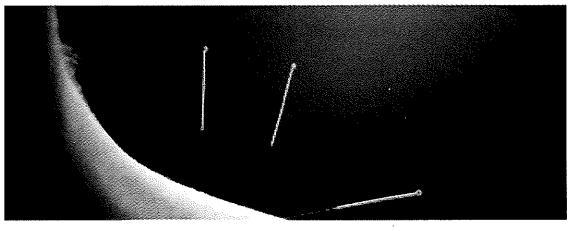
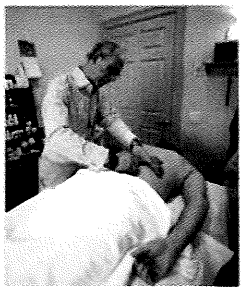
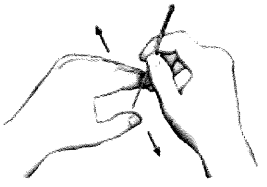
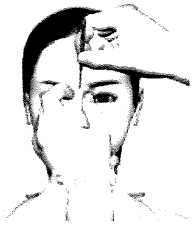


图 1 - 42 动静留针
Fig. 1 - 42 Static and active retention of the needle









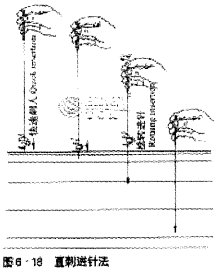
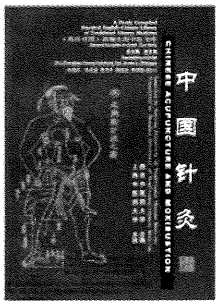
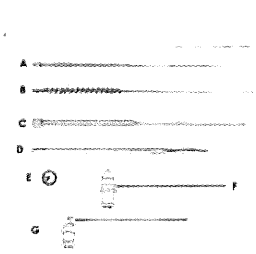
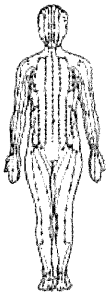
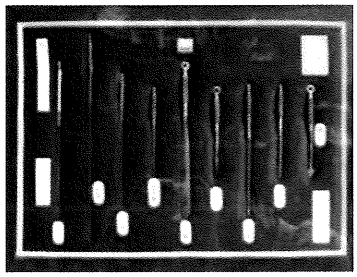


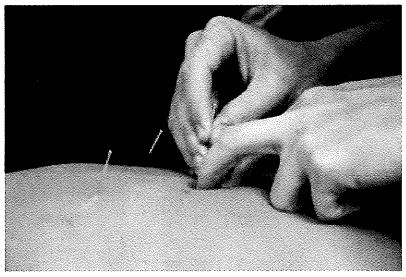
图 6 - 18 直刺进针法
Fig. 6 - 18 Perpendicular insertion of the needle

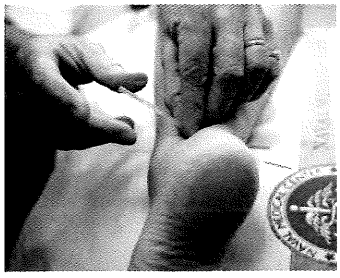






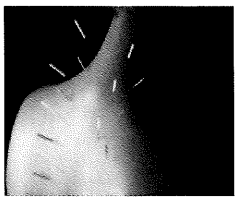






Coalition for Safe Acupuncture Practice

When is Dry Needling Acupuncture?



The short answer is "Always."

Dry needling is a pseudonym for a brief course of study in myofascial acupuncture also known as *ashi* acupuncture and trigger point acupuncture.[7] Three important studies, Trigger Points and Classical Acupuncture Points, Parts 1,2,3 (P.T. Dorsher, J. Fleckenstein) explore the relationship of Ashi or Acupuncture points to myofascial trigger point regions. In the first part of the study, myofascial trigger point regions were demonstrated to have strong (93.3%) anatomic correspondences with classical acupuncture points.[1] The second portion of this study exam ined the clinical correspondences of trigger point regions and classical acupuncture points in the treatment of both pain and somatovisceral disorders, and found they had ~ 97 % correlation for treating pain conditions and over 93 % correlation in treating somatovisceral conditions.[2] The third portion of the study concluded that the strong (up to 91 %) consistency of the distributions of trigger point regions' referred pain patterns to acupuncture meridians provides a third line of evidence that trigger points most likely represent the same physiological phenomenon as acupuncture points in the treatment of pain disorders.[3]

Ashi Point Needling is Myofascial Trigger Point Needling is Acupuncture. Dry Needling is Acupuncture, too.

The National Commission for the Certification of Acupuncture and Oriental Medicine (NCCAOM), the certifying board for Acupuncture licensure, completed a job task analysis in 2003 and again in 2008. The analysis documented the prevalence of actual use of Dry Needling techniques, that is the treatment of trigger points, motor points and/or ashi points with acupuncture needles, by practicing acupuncturists. In 2003, 82% of acupuncturists surveyed used needling of trigger points in patients that presented with pain. Of the patients that present for acupuncture treatment, it is estimated that 56% present with trigger point pain.[4]

These findings document that acupuncturists are well trained to use and have consistent historical usage of trigger and motor point "dry needling" treatment. Dry needling represents a substantial daily practice among American acupuncturists.[5]

Medicare reinforces these findings by its use of ICD-9 (International Classification of Disease, 9th Ed.) and CPT (Current Procedural Terminology) coding in its claims reimbursement. While litigating a case involving coding for Dry Needling, Assistant U.S. Attorney Kevin Doyle said "The only code for Medicare that would cover something like Dry Needling would be an Acupuncture code." [6]

SOURCES CITED: 1, 2, 3. *Elsevier-Germany Online Journals.* Web. 30 Dec. 2011. <http://elsevier.isoftmedia.de/inhalt.php?/lan~eng/site~journalg/journal~4/name~1_09/article~5800132.html>. **4,5.** "Position Paper on Dry Needling | Acupuncture Association of Colorado." *Acupuncture Association of Colorado | Acupuncture Denver | Find an Acupuncturist.* Web. 31 Dec. 2011. <http://acucol.com/2011/03/position-paper-on-dry-needling/>. **6.** Dritschilo, Gordon. "Doctor Settles Billing Case: Rutland Herald Online." *RutlandHerald.com | Rutland Herald | Rutland News, Rutland Sports, Rutland Real Estate, Vermont Jobs.* Web. 28 Dec. 2011. <http://www.rutlandherald.com/article/20111025/NEWS01/710259964/0/business>. **7.** Janz, Stephen. "Acupuncture by Another Name." *Australian Jn of Acupuncture and Chinese Medeicine* 6.2 (2011). Web. 28 Dec. 2011. <http://acupuncture.org.au/Portals/0/AJACMFiles/PDFs/Vol%206%20Iss%202/AJACM%202011%206%202%20Acupuncture%20By%20Another%20Name%20-%20Janz%20&%20Adams.pdf>.

The Coalition for Safe Acupuncture Practice seeks to bring public and media attention to this public health issue by education, petition and Public Demonstration.

Please visit us on Facebook at Coalition for Safe Acupuncture Practice, where you can also sign the CSAP Petition. Or write us at CSAP@Aardvarksfly.com. Thanks!

COALITION for SAFE ACUPUNCTURE PRACTICE

May 17, 2011

AAAOM
全美中醫公會
American Association of
Acupuncture & Oriental Medicine

American Association of Acupuncture and Oriental Medicine (AAAOM) Position Statement on Trigger Point Dry Needling (TDN) and Intramuscular Manual Therapy (IMT)

1. **Acupuncture as a technique is the stimulation of specific anatomical locations on the body, alone or in combination, to treat disease, pain, and dysfunction.**

2. **Acupuncture as a technique includes the invasive or non-invasive stimulation of said locations by means of needles or other thermal, electrical, light, mechanical or manual therapeutic method.**

3. **Acupuncture as a field of practice is defined by the study of how the various acupuncture techniques can be applied to health and wellness.**

4. **Trigger Point Dry Needling and Intramuscular Manual therapy are by definition acupuncture techniques.**

5. **Trigger Point Dry Needling and Intramuscular Manual Therapy are by definition included in the Field of Acupuncture as a field of practice.**

The AAAOM endorses the educational standards set for the practice of Acupuncture by the United States Department of Education recognized Accreditation Commission of Acupuncture and Oriental Medicine (ACAOM).

The AAAOM endorses the Institute for Credentialing Excellence (ICE)'s National Commission on Certifying Agencies (NCCA) recognized certification standards set forth by the National Certification Commission of Acupuncture and Oriental Medicine (NCCAOM).

Recently, it has come to the attention of the AAAOM that regulatory boards have started to recognize Acupuncture by other names, such as "dry needling" and "trigger point dry needling." Forty-four (six pending) states plus the District of Columbia have already statutorily defined Acupuncture and most have defined the educational and certification standards required for licensure by the widely accepted aforementioned standards. Current medical literature is consistent with the definitions of Acupuncture provided by the state practice acts and the AAAOM, which clearly identifies "dry needling" as Acupuncture.[1] [2] [3] [4] [5] [6] [7] [8] [9] [10] [11] [12] [13]

Trigger Point Dry Needling and Intramuscular Manual Therapy are re-titlings and re-packagings of a subset of the acupuncture techniques described in the Field of Acupuncture as "*ashi* point needling." A reasonable English translation of *ashi* points is "trigger points", a term used by Dr. Janet Travell in her landmark 1983 book *Myofascial Pain Dysfunction: The Trigger Point Manual*[6]. Dorsher et al[4], determined that of the 255 trigger points, listed by Travell and Simons, 234 (92%) had anatomic correspondence with classical, miscellaneous, or new Acupuncture points listed in Deadman et al[7].

Other authorities describe dry needling as Acupuncture. Mark Seem discussed dry needling in *A New American Acupuncture* in 1993[8]. Matt Callison describes dry needling in his *Motor Points Index*[9] as does Whitfield Reaves in *The Acupuncture Handbook of Sports Injuries and Pain: A Four Step Approach to Treatment*[10]. Yun-tao Ma, author of *Biomedical Acupuncture for Sports and Trauma Rehabilitation Dry Needling Techniques,* describes dry needling as Acupuncture and provides a rich historical explanation[11]. Chan Gunn sought to create language more readily accepted in the West in a 1980 article[12]. These examples make it clear that there is a literary tradition in the Field of Acupuncture that uses the term "dry needling" as a synonym for a specific, previously established Acupuncture technique.

The AAAOM has the following additional specific concerns: 1) No standards of education have been validly determined to assure that Physical Therapists (PT) using TDN are providing the public with a safe and effective product; 2) There is a clear effort to redefine identical medical procedures and thereby circumvent or obscure

Attachment 6

AAAOM
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established rules and regulations regarding practice; and 3) In many states, addition of TDN to PT practice is a scope expansion that should require legislative process, not a determination by a PT Board.

The U.S. Department of Education recognizes ACAOM as the sole accrediting agency for Acupuncture training institutions as well as their Master's and Doctoral Degree programs.[13] [14] Training in Acupuncture, which has been rigorously refined over the course of hundreds of years internationally and forty years domestically, is well established and designed to support safe and effective practice.[15] [16] Attempts to circumvent Acupuncture training standards, licensing or regulatory laws by administratively retitling acupuncture as "dry needling" or any other name is confusing to the public, misleading and creates a significant endangerment to public welfare.

The actual risk has already been investigated by at least one malpractice insurance company that has stated it will cancel polices for Physical Therapists "engaging in a medical procedure for which they have no adequate education or training."[17] Recent actions by state medical regulatory authorities have identified and acted upon the aforementioned risk.[3]

In conclusion, the AAAOM strongly urges legislators, regulators, advisory boards, advocates of public safety, and medical professional associations to carefully consider the impact of these actions.

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[1] http://www.ncbi.nlm.nih.gov/pubmed/15108608

[2] http://www.Acupuncture.org.au/zone_files/Download_Icons/jing-luo_march_2011_web.pdf pg. 10

[3] http://www.oaaom.com/wp-content/uploads/2010/06/DryNeedling.pdf

[4] Dorsher PT. *Trigger Points And Acupuncture Points: Anatomic And Clinical Correlations.* Medical Acupuncture. 2006;17(3).

[5] Deadman P, Al-Khafaji M, Baker K. A Manual of Acupuncture. Kingham, Oxfordshire Journal of Chinese Medicine Publications; 1998.

[6] Travell J, Simons D. Myofascial Pain Dysfunction: The Trigger Point Manual. Philidelphia, PA: Lippincott Willimas & Wilkins; 1983.

[7] Deadman P, Al-Khafaji M, Baker K. A Manual of Acupuncture. Kingham, Oxfordshire Journal of Chinese Medicine Publications

[8] Seem M. A New American Acupuncture: Acupuncture Osteopathy, the Myofascial Release of the Bodymind. Boulder, CO: Blue Poppy Press; 1993.

[9] Callison M. Motor Point Index: An Acupuncturist'sGuide to Locating and Treating Motor Points San Diego, CA: AcuSport Seminar Series LLC; 2007.

[10] Reaves W, Bong C. The Acupuncture Handbook of Sports Injuries & Pain. Boulder, CO: Hidden Needle Press; 2009.

[11] Ma, Yun-tao. Biomedical Acupuncture for Sports and Trauma Rehabilitation Dry Needling Techniques. New York: Elsevier; 2010.

[12] Gunn CC, Milbrandt WE, Little AS, Mason KE. *Dry Needling of Muscle Motor Points for Chronic Low-Back Pain: A Randomized Clinical Trial With Long-Term Follow-Up.* Spine. 1980;5(3):279-91.

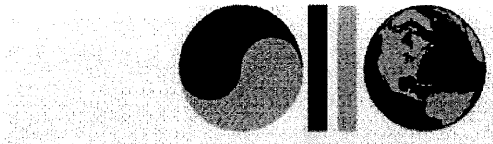
[13] http://ope.ed.gov/accreditation/

[14] http://www.acaom.org/about/

[15] http://www.acaom.org/documents/accreditation-manual.pdf

[16] http://www.nccaom.org/applicants/eligibility-requirements

[17] Letter from Allied Professional Services [on file at AAAOM]



ALLIED PROFESSIONALS INSURANCE COMPANY
A RISK RETENTION GROUP, INC.

December 15, 2009

Ms. Kathleen Haley
Executive Director
State of Oregon Medical Board
1500 SW 1st Ave., Suite 620
Portland, OR 97201-5847

Dear Ms. Haley:

We are writing on behalf of Allied Professionals Insurance Company, a Risk Retention Group ("APIC"). APIC is a federal risk retention group that provides malpractice insurance to physical therapists. It has come to APIC's attention that the Oregon Physical Therapist Licensing Board recently determined that the technique of "dry needling" falls within the scope of practice of physical therapy. This determination concerns APIC not only on a malpractice perspective, but also for its effect on public health and safety.

According to the World Health Organization, the term "acupuncture" means to puncture with a needle. "Dry needling" is a term that was developed to define the technique of placing an acupuncture needle into a muscle trigger point rather than injecting the trigger point with lidocaine or cortisone. Dry needling focuses on releasing muscle tension by treating specific trigger points, alleviating nerve tissue irritation by reducing the nerve impulse, or stimulating local blood supply where it may be naturally poor, such as the junction between tendons or ligaments and bone. It became known a "dry" needle because nothing was injected. Dry needling is a derivative of acupuncture and defined by the World Health Organization as "acupuncture."

In fact, one of the pioneers of the dry needling technique, Chan C. Gunn, stressed that many trigger points were close to or identical to acupuncture points. Mr Gunn believed that Western practitioners would better accept the technique if the point locations were described in anatomical rather than traditional Chinese medical terms.[1]

Proponents of the addition of dry needling to the scope of physical therapy maintain that trigger point dry needling does not have any similarities to acupuncture other than using the same tool. These same proponents of the technique redefine traditional Chinese medicine as being based on a traditional system of energetic pathways and the goal of acupuncture to balance energy in the body. They emphasize the channel relationship of acupuncture points, de-emphasize or completely exclude the use of ASHI points, and emphasize that acupuncture is based on the energetic concepts of Oriental medicine diagnosis. They therefore define dry needling as different and distinct from acupuncture because it is based on Western anatomy.[2]

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[1] Gunn, CC et al. *Spine*, 1980

[2] Hobbs, Valerie, DiplOM, LAc, *Dry Needling and Acupuncture Emerging Professional Issues*

However, these proponents fail to recognize that acupuncture schools teach both "western" neurophysiological concepts along with "traditional" meridian concepts. As such, acupuncturists are highly trained within both fields of medicine. In fact, the profession of Chinese medicine utilizes neurophysiological principles. As such, there is no such distinction between "eastern" and "western" acupuncture.

Dry needling certainly is a contentious issue. However, the issue needs to be ultimately viewed from the perspective of public health and safety. Currently, the leading dry needling courses being offered in the United States include the Travell Series through Myopain Seminar in Maryland, and dry needling courses offered by the Global Education of Manual Therapists located in Colorado.

The Travell Series is comprised of an 80-hour course on myofascial trigger points and a 36-hour course on dry needling. The course is designed for licensed healthcare practitioners including acupuncturists.[3] The dry needling course offered by the Global Education of Manual Therapists is a 27.5 hour introductory course with an option for another 27.5 hour level two seminar.[4]

Licensed acupuncturists typically receive at least 3000 hours of education.[5] The dry needling courses currently being offered, including the Travell Series and the courses offered by the Global Education of Manual Therapists, not only allow physical therapists to use needles on patients without sufficient training, but constitute a public health hazard.

California, Hawaii, New York, North Carolina, and Tennessee, all prohibit physical therapists from performing dry needling. In addition, the state of Florida disallows physical therapists from using any technique which ruptures the skin.

In California, physical therapists recognize that invasive procedures clearly move beyond the scope and training of physical therapy. In some instances, they hire licensed acupuncturists to treat patients. Many physical therapists respect the fact that use of needles is both an invasive procedure beyond the professional scope of physical therapy and is directly related to the practice of acupuncture.

According to Ben Massey Jr., PT, MA, the Executive Director of the North Carolina Board of Physical Therapy Examiners, "Dry needling is a form of acupuncture. In North Carolina, a practitioner who performs acupuncture must have a license from the North Carolina Board of Acupuncture."[6]

Oregon defines "acupuncture" as "Oriental health care practice used to promote health and to treat neurological, organic or functional disordered by the ***stimulation of specific points***

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[3] http://www.myopainseminars.com/seminars/travell/index.html

[4] http://www.gemtinfo.com/physical-therapy/Trigger-Point-Dry-Needling-Level-II-Training/page18.html

[5] http://aaaonmonline.org/pressroom.asp?pagenumber=48266

[6] http://aaaonmonline.org/pressroom.asp?pagenumber=48266

on the surface of the body by the insertion of needles..." [7] (Emphasis added). As discussed above, dry needling focuses on releasing muscle tension by treating specific trigger points, alleviating nerve tissue irritation by reducing the nerve impulse, or stimulating local blood supply where it may be naturally poor. As such, dry needling falls squarely within the Oregon definition of "acupuncture", as it involves the insertion of needles on the surface of the body to stimulate specific points.

Physical therapy state boards of Maryland, New Mexico, New Hampshire and Virginia have determined that dry needling falls within the scope of physical therapy in those states. However, the Oregon statute defining "acupuncture" is distinguishable from these states' statute.

For example, the New Mexico Acupuncture and Oriental Medicine Practice Act defines acupuncture as "the use of needles inserted into and removed from the human body for the prevention, cure or correction of any disease, illness, injury, pain, or other condition by controlling and regulating the flow and balance of energy and functioning..."[8]

Proponents of the addition of dry needling to the scope of physical therapy point out that dry needling is not to control and regulate the flow and balance of energy and is not based on Eastern esoteric and metaphysical concepts. As such, based on the definition of "acupuncture" as set forth in the New Mexico Acupuncture and Oriental Medicine Practice Act, the physical therapy state board determined that dry needling falls within the scope of physical therapy practice.

However, unlike the New Mexico statute, ORS 677.757 is not narrowly tailored to limit the practice of "acupuncture" to the control and regulation of the flow and balance of energy and functioning.

Moreover, the Oregon Physical Therapist Licensing Board Administrative Rules does not provide for any statutory authority to physical therapists to perform dry needling.[9] In fact, ORS 848-040-0100(8) provides that "'Physical therapy intervention' means a treatment or procedure and includes but is not limited to: therapeutic exercise; gait and locomotion training; neuromuscular reeducation; manual therapy techniques (including manual lymphatic drainage, manual traction, connective tissue and therapeutic massage, mobilization/manipulation of soft tissue or spinal or peripheral joints, and passive range of motion); functional training related to physical movement and mobility in self-care and home management (including activities of daily living (ADL) and instrumental activities of daily living (IADL)); functional training related to physical movement and mobility in work (job/school/play), community, and leisure integration or reintegration (including IADL, work hardening, and work conditioning); prescription, application, and, as appropriate, fabrication of devices and equipment (assistive, adaptive, orthotic, protective, or supportive); airway clearance techniques; integumentary repair and protective techniques; electrotherapeutic modalities; physical agents and mechanical modalities;

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[7] ORS 677.757(1)(a)

[8] New Mexico Statutes Annotated 1978, Chapter 61, Professional and Occupational Licenses, Article 14A, Acupuncture and Oriental Medicine Practice 3, Definitions

[9] ORS 848-040-0100(8)

and patient related instruction and education." For the Oregon Physical Therapy Licensing Board to determine that dry needling falls within the scope of practice for its physical therapists means that the Oregon Physical Therapy Licensing Board is ignoring the definition of "acupuncture" in ORS 677.757, and is making a policy to include dry needling by a rule, rather than leaving the physical therapy profession to sponsor and pass a bill that explicitly changes state physical therapy law.

Additionally, the Oregon Physical Therapy Licensing Board's reliance on ORS 848-040-0145 (2), which provides that "A physical therapists or physical therapist assistant shall perform, or attempt to perform physical therapy interventions only with qualified education and experience in that intervention"[10], to justify that dry needling is within in scope of physical therapy is not only overreaching but almost irresponsible and dangerous. The Oregon Physical Therapist Licensing Board Administrative Rules do not provide further standards or guidelines regarding dry needling education and/or certification. As such, it is impossible to determine what is considered "qualified education and experience" in dry needling. It is a public health hazard to allow physical therapists to use needles on patients without sufficient training.

Based on the foregoing, APIC will not provide malpractice insurance for any physical therapist who inserts needles and/or utilizes the technique of dry needling.

Thank you for your professional courtesies in this regard. Should you have any further questions or concerns, please do not hesitate to contact me.

Sincerely yours,

Rick A. Cigel

Rick A. Cigel
Counsel

[10] ORS 848-040-0145(2)

CCAOM

Council of Colleges of
Acupuncture and Oriental Medicine

Council of Colleges of Acupuncture and Oriental Medicine*

Position Paper on Dry Needling

It is the position of the Council of Colleges of Acupuncture and Oriental Medicine (CCAOM) that dry needling is an acupuncture technique.

Rationale

A recent trend in the expansion in the scopes of practice of western trained health professionals to include "dry needling" has resulted in redefining acupuncture and re-framing acupuncture techniques in western biomedical language. Advancement and integration of medical technique across professions is a recognized progression. However, the aspirations of one profession should not be used to redefine another established profession.

In addition proponents of "dry needling" by non-acupuncture professionals are attempting to expand trigger point dry needling to any systemic treatment using acupuncture needles and whole body treatment that includes dry needling by using western anatomical nomenclature to describe these techniques. It is the position of the CCAOM that these treatment techniques are the *de facto* practice of acupuncture, not just the adoption of a technique of treatment.

Terminology

The invasive procedure of dry needling has been used synonymously with the following terms:

Trigger Point Dry Needling
Manual Trigger Point Therapy, when using dry needling
Intramuscular Dry Needling
Intramuscular Manual Therapy, when using dry needling
Intramuscular Stimulation, when using dry needling

History

The system of medicine derived from China has a centuries-long continuous distinct practice with an extensive literature over 2000 years old. After President Nixon's visit to China in the early 1970s, public interest in and demand for

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acupuncture resulted in the establishment of first-professional degrees in acupuncture in the United States. Today over 50 accredited[1] first-professional colleges teach a diversity of styles of health care utilizing acupuncture, Chinese herbology, manual techniques such as tuina (Chinese therapeutic massage), nutrition, and exercise/breathing therapy. Individuals who attain this degree undergo a rigorous training program at a minimum standard of three academic years that contains 450 hours in biomedical science (biology, anatomy, physiology, western pathology, and pharmacology), 90 hours in patient counseling and practice management, and 1365 hours in acupuncture. Of the 1365 hours in acupuncture, 660 hours must be clinical hours.

Acupuncture is a system of medicine that utilizes needles to achieve therapeutic effect. The language used to describe and understand this effect is not limited and is articulated in both traditional and modern scientific terms. The National Institutes of Health has recognized the efficacy of acupuncture in its consensus statement of 1997[2] and continued funding of research. It is clear that other professions such as physical therapy and others also recognize the efficacy of acupuncture and its various representations such as dry needling due to the fact that they are attempting to use acupuncture and rename it as a physical therapy technique.

Dry needling is an acupuncture technique

As a system of treatment for pain, acupuncture relies on a category of points derived from the Chinese language as "*ashi*" (阿是) points. "*Ashi*" point theory describes the same physiological phenomenon identified as "trigger points," a phrase coined by Dr Janet Travell[3] and dates to the Tang Dynasty (618-907). While Dr. Travell coined the phrase "trigger point", the physiological phenomenon has been long known to acupuncturists. Dr. Travell herself had contact with acupuncturists and chiropractors interested in acupuncture in the Los Angeles area in the 1980s. Dr. Mark Seem, author of *A New American Acupuncture*[4], discussed the similarity of their techniques in the 1990s.[5]

Modern contributors from the field of acupuncture in the specialization of dry needling techniques are:

Dr. Mark Seem, Ph. D., L. Ac., published the textbook *A New American Acupuncture* covering the topic of dry needling in 1993. His books have been published for over two decades.

Matt Callison, L. Ac., is the founder of the Sports Medicine Acupuncture® certification program and the author of *Motor Points Index*. The continuing education certification program is available to licensed acupuncturists through a private seminar company and through postgraduate studies at the New England School of Acupuncture.

Whitfield Reaves, L. Ac. is the author of *The Acupuncture Handbook of Sports Injuries and Pain: A Four Step Approach to Treatment.* He also offers a

postgraduate continuing education program in Sports Acupuncture only for licensed acupuncturists.

From the above sources it is apparent that acupuncture has an established history of using treatment utilizing what are now labeled trigger points.

Documented practice of "dry needling" by acupuncturists

The National Commission for the Certification of Acupuncture and Oriental Medicine (NCCAOM), the certifying board for acupuncture, completed a job task analysis in 2003 and again in 2008. The analysis documented the prevalence of actual use of dry needling techniques, i.e. the treatment of trigger points or motor points with acupuncture needles, by practicing acupuncturists. In 2003, 82% of acupuncturists surveyed used needling of trigger points in patients that presented with pain. Of the patients that present for acupuncture treatment, it is estimated that 56% present with trigger point pain. The others present for non-pain conditions such as non-trigger point pain, digestives disorders, infertility and many other conditions. The other 18% of acupuncturists used acupuncture needling techniques in non-trigger point locations. These findings document that acupuncturists are well trained to use and have consistent historical usage of trigger and motor point "dry needling" treatment. Dry needling represents a substantial daily practice among American acupuncturists.

History of "dry needling" in North America

Dr. Chan Gunn, M.D., is the founder of dry needling in Canada. He wrote in 1976, "As a first step toward acceptance of acupuncture by the medical profession, it is suggested that a new system of acupuncture locus nomenclature be introduced, relating them to known neural structures."[6] One may reasonably infer from this statement that Dr, Gunn believed that in order for acupuncture to be accepted in Western medicine, the technique would need to be redefined. Using a different name for the same technique does not rise to the level of creating a new technique. Dr. Chan Gunn's dry needling seminars are only four days in length.

Jan Dommerholt has published extensively on the technique and teaches dry needling to both western trained health professionals and licensed acupuncturists, but his teaching has been focused on the profession of Physical Therapy (PT). He argues that dry needling is a new emerging western technique described in western scientific terms. He is also attempting to redefine acupuncture based solely on eastern esoteric concepts.

A current author and provider of dry needling courses, Yun-tao Ma, Ph.D., extends dry needling beyond trigger points to include acupuncture points. He describes the points according to the neuroanatomical location and effects and calls them "Acu reflex" points. It is this adaptation and renaming of acupuncture to provide total body treatment that poses the greatest risk to the public, as it circumvents established standards for identical practice, i.e., acupuncture, without the rigorous training of acupuncture and the licensing of such.

It is the position of the CCAOM that any intervention utilizing dry needling is the practice of acupuncture, regardless of the language utilized in describing the technique.

State Board of Medicine complaints against acupuncturists for dry needling

In 2009, a physical therapist submitted a complaint to the Maryland Board of Acupuncture concerning the use of the term dry needling in chart notes by an acupuncturist. The Maryland Board of Acupuncture correctly dismissed the complaint because the procedure was done by a licensed acupuncturist trained in the use of dry needling, *i.e.,* acupuncture.

In filing the complaint, the physical therapist was not asserting that the acupuncturist caused any harm or potential of harm to the patient. Rather, the physical therapist asserted that the acupuncturist used proprietary language that was unique to physical therapy, when in fact the acupuncturist was using language that was common across professions. The Little Hoover Commission, in its 2004 report to the California legislature concluded, "interactions with other health care providers, including collaboration and referrals, as well as with many members of the public, benefit from the use of common, Western-based diagnostic terminology"7

Summary Position of the CCAOM on Dry Needling

It is the position of the Council of Colleges of Acupuncture and Oriental Medicine (CCAOM) that dry needling is an acupuncture technique.

It is the position of the CCAOM that any intervention utilizing dry needling is the practice of acupuncture, regardless of the language utilized in describing the technique.

Adopted November 2010
Updated May 2011

[1] The Accreditation Commission for Acupuncture and Oriental Medicine (ACAOM) is recognized by the U.S. Department of Education to accredit colleges of acupuncture and Oriental medicine and authorizes such colleges to confer Master's level first-professional degrees.

[2] http://consensus.nih.gov/1997/1997Acupuncture107html.htm.

[3] Travel, Janet G., and David G. Simons. Myofascial pain dysfunction: the trigger point manual. Lippincott Willimas & Wilkins, 1983, Print.

[4] Seem, Mark. A new American acupuncture: acupuncture osteopathy, the myofascial release of the bodymind. Blue Poppy Press, 1993. Print.

[5] Private communication of October, 2007 with Whitfield Reaves, L. Ac., who attended study groups with Dr. Travell in the 1980s, and in a letter from Dr. Mark Seem to Jan Dommerholt November 11, 2007. Seem relates his invitation and demonstration of acupuncture "dry needling" techniques to Dr. Travell in New York City in the 1990s.

[6] Gunn, CC, Ditchburn FG, King MH, Renwick GJ, *Acupuncture loci: a proposal for their classification according to their relationship to known neural structures*, Am J Chin Med, 1976 Summer; 4(2): 183-95.

[7] Milton Marks "Little Hoover" commission on California State Government Organization and Economy by the UCSF Center for the Health Professions, *Acupuncture in California: Study of Scope of Practice*, May 2004, pg. 13.

Acupuncture by Another Name: Dry Needling in Australia

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ABSTRACT

Like acupuncture, dry needling involves the insertion of acupuncture needles into specific points on the body to improve health. Unlike acupuncture, the practice of dry needling is unregulated in Australia. This paper challenges the notion that dry needling is not a part of acupuncture practice and also examines the risks associated with the practice of dry needling from a public health perspective. The practice of acupuncture and dry needling are first examined and compared to identify commonalities. A review into the incidence of risks of dry needling reveals very limited literature with only one case report and no review articles identified. Based on the similarities between acupuncture and dry needling, the extensive literature on the serious risks of acupuncture is extrapolated to evaluate the risks of dry needling. Dry needling is not a new or separate practice to acupuncture; rather it is a subsystem of musculoskeletal acupuncture which has been practised continuously for at least 1 400 years. Dry needling is a pseudonym for a brief course of study in myofascial acupuncture also known as *ashi* acupuncture and trigger point acupuncture. Dry needling is likely to result in an increased incidence of serious risks, particularly pneumothorax, due to the short training courses and deep needling techniques which typify the practice. In the interest of public health and safety, the practice of dry needling should be restricted to suitably qualified practitioners.

KEYWORDS acupuncture, dry needling, myofascial acupuncture, trigger point acupuncture, education standards, regulation, serious risk, physiotherapy, Australia.

Background

Australia became the first country in the western world to implement the statutory regulation of acupuncture under a restriction of title system in the State of Victoria in 2001.[1] The current minimum standard for acupuncture registration with the Chinese Medicine Registration Board of Victoria is the completion of an approved four to five year bachelor's degree or a three year graduate-entry master's degree.[2] This same standard had been used in Victoria for acupuncture endorsement by the other health professions, except for chiropractors and medical practitioners which have adopted a lower standard.[3]

Although at present limited to just one State,[4] statutory regulation of the acupuncture profession will be extended to a uniform national system—the National Registration and Accreditation Scheme for the Health Professions (NRAS)—from 1 July 2012.[5] NRAS provides for a separate board for each of the 14 registered health professions.[6] Under the Health Practitioner National Law Act 2009, it is an offence to use a restricted title or to hold out to practise in a registered health profession unless the practitioner is suitably registered or endorsed to do so.[5] Unique to this scheme is that, in addition to the Chinese Medicine Board of Australia (CMBA), each of the other 13 boards may (but is not obliged to) develop its own standard for acupuncture endorsement. A registered health practitioner who meets their respective board's acupuncture endorsement standard may have their registration endorsed

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Attachment 9

as such (after 1 July 2012) and will be able to use the title 'acupuncturist' even though they are not registered with the CMBA.[5] The Physiotherapy Council of Australia is developing an accreditation standard for acupuncture endorsement under the NRAS on behalf of six other national boards, to take effect from 1 July 2012.[7,8]

Introduction

The statutory regulation of acupuncture which commenced in 2001 in the State of Victoria followed research demonstrating that serious risks to public health and safety were posed by acupuncture[9] and that these risks could be addressed by regulation.[4,9] This proposition had to be demonstrated again in 2008 as a prerequisite for acupuncture and Chinese medicine to be incorporated into the NRAS.[10] Since 2002 there has been an increase in the practice of acupuncture under the term 'dry needling'.[11] Both registered and unregulated practitioners commonly complete two or three day courses under the titles 'dry needling' or 'myofascial dry needling'[11] rather than completing the three to four year degree programs leading to registration or endorsement as an acupuncturist.[3] Provided they do not use the protected title 'acupuncturist' nor hold out (advertise) to practise acupuncture, these practitioners operate outside the standards-setting or regulatory environment which protects the public from poorly-practised acupuncture.[11]

Practitioners of dry needling claim that they are not practising acupuncture as their practice is based upon biomedical research into the treatment of myofascial trigger points (MTrPs) and has no relationship with classical Chinese acupuncture theory and practice.[12] It is claimed that the only similarity between dry needling and acupuncture is the use of the same tool (the acupuncture needle).[12,13] This paper will examine the serious risks of dry needling and acupuncture to identify if the practice of dry needling poses lesser risks than the practice of acupuncture and therefore should not be subject to regulation. The proposition that dry needling is a pseudonym for the practice of musculoskeletal acupuncture and should be regulated under the existing acupuncture provisions of the NRAS will also be evaluated.

Acupuncture

Acupuncture involves the insertion of fine solid acupuncture needles into specific points on the body to improve health.[14] The selection of points may be based upon traditional medical systems, biomedical research into point functions, or point prescriptions.[15] Despite acupuncture's long history of practice originating in China[16], its biomedical mechanism(s) are not fully understood.[17] Traditional explanatory models of acupuncture relate to the concepts of qi, blood, and channels (meridians).[18] Stimulating an appropriate acupuncture point removes restriction to the flow of qi and blood in the channels, restores unobstructed circulation and benefits health.[19] Acupuncture points can affect the local tissue in which they are located or have effects on distant parts of the body or on systemic function.[19] Acupuncture is traditionally used for pain and tissue trauma as well as for systemic health complaints.[20] A wide variety of needling techniques and non-needle point-stimulation methods may be used.[19] This classical Chinese understanding of the mechanism of acupuncture and its therapeutic application initially developed without an understanding of modern biomedical perspectives of anatomy and physiology .

A biomedical understanding of the mechanism of acupuncture has been sought since at least the mid 1940s.[21] Immuno-inflamatory mechanisms, hypothalamic-pituitary axis influence, pain control via endogenous pain control systems, neuroplasticity, and myofascial trigger points are all thought to be involved, although none of these models fully explain how acupuncture works.[17,22] Practitioners who emphasise a biomedical understanding of acupuncture in their practice often refer to their practice as 'medical acupuncture'[23] or 'western acupuncture'.[24]

It is also possible that the classical acupuncture channels may actually exist in some physical form.[25,26] Research is exploring the role of connective tissue and the correlation of fascia to the acupuncture channels.[17,25,26] In such a model the 'qi' of Chinese medicine may relate to a combination of nerve signals, the flow of pacacrine signalling molecules, electrical signalling through gap junctions among perineural cells and the distribution of mechanical forces.[26] Should the role of fascia be found to correlate with classical meridians, then much of the current biomedical research may need to be re-interpreted in a holistic model, perhaps in a way similar to the classical Chinese model.[26]

Dry needling

Dry needling has been variously defined according to its context. Initially the term 'dry needling' was used to differentiate the insertion of a solid acupuncture needle into the body for therapeutic effect from the injection of a substance through a hollow needle.[27,28] In the text Medical Acupuncture, Bekkering and van Bussel explain[28] "Acupuncture is in principle a 'dry' therapy as no pharmacological substances are administered through the needle.". 'Dry' acupuncture works neurophysiologically differently to 'wet' acupuncture where local anaesthetic is usually injected into a point.[28]

In contemporary literature the term 'dry needling' is typically used to refer to the needling of MTrPs with an acupuncture needle.[29] MTrPs are 'hyperirritable spots in skeletal muscle that are associated with a hypersensitive palpable nodule in a taut band'.[30] When a needle is inserted into a MTrP a local twitch

response occurs as well as referred pain.[29] MTrPs are associated with myofascial pain syndrome (MPS), a common source of acute and chronic pain worldwide.[29] MTrPs were first described in the West by John Kellegren in 1938.[31] He identified small tender points in muscle which reproduced the pain of myalgia when pressed. This pain was typically felt away from the point rather than just locally and would resolve when injected with a local anaesthetic. Janet Travel later termed these points trigger point and labelled the pain associated with them MPS.[27]

The practice of deactivating trigger points with local anaesthetics (wet needling) remains common.[32] However, in 1979 Carl Lewit had demonstrated that inserting a dry needle deeply and accurately into a MTrP was effective in treating musculoskeletal pain.[27] Over the past decade or so[33] the use of dry needling (acupuncture) has become popular to treat MTrP.[33,34] Physical therapists practise dry needling throughout the world.[35] In Australia, dry needling courses are offered to physiotherapists, chiropractors, osteopaths, podiatrists, medical practitioners, nurses, massage therapists and other health professionals.[3] Part of the popularity of dry needling may be linked to the ease with which acupuncture needles can be obtained by non-medical practitioners compared to the restrictions based on obtaining or injecting local anaesthetics.[12]

The term dry needling is not only concerned with MTrPs. Dr Chan Gunn has developed another system for treating MPS and other conditions which he has named Intramuscular Stimulation (IMS) to differentiate it from other needling practices.[12,36] Gunn proposes that examination, diagnosis, and treatment with acupuncture needles should be based on a radiculopathy model.[36] In this model taut bands in muscles are treated with acupuncture needles and special attention is given to releasing shortened paraspinal muscles that may be compressing a disc, irritating a nerve root and, according to Gunn, initiating the distal muscle pathology.[12,36] Points are used both locally at the affected spinal segment as well as distally within the respective dermatome or myotome.[37]

Acupuncture and dry needling

Numerous needling methods incorporating the approach of both MTrP and IMS are described in both classical and contemporary Chinese acupuncture literature. In the classical Chinese medical model MTrP are referred to as *ashi* points and were described by Sun Si Miao in the Thousand Ducat Prescriptions in 652 CE.[19,34] Baldry[31] states that trigger point acupuncture is the same as this continuously-practised ancient *ashi* acupuncture. In ancient texts cutaneous, shallow and deep acupuncture methods are described for treating numbness of the skin, muscle constriction, spasms and pain.[38] The repeated needling and reinserting of a needle into a muscle in different directions to treat pain, numbness and debility of muscle tissue is described as one of the ancient five needling methods.[38] This latter approach seems similar to that used by Gunn.[37] Biomedical research into acupuncture and, in particular, the relationship between spinal segments and dermatomes or myotomes was reported in 1975 and was a component of a standard acupuncture textbook in 1981.[39]

Injection therapy was considered a relatively new treatment in Chinese acupuncture in 1974[40] and is indicated for 'positive response points' which may be flat, round, strand like or nodular in shape.[40] Positive response points should be searched for by light palpation over the back, chest, abdomen and limbs. Of particular importance are the points on the channels which are 0.5 units and 1.5 units lateral to the spine respectively.[40] These points themselves resemble MTrP, and the systematic approach of examination and treatment is conducted without particular regard to other classical concepts such as qi and blood. These points and their selection seem similar to the systematic approach of examination and treatment, especially paying attention to spinal pathology, advocated by Gunn for his IMS system.[36]

Gunn states that IMS is not acupuncture because 'IMS requires a medical examination and diagnosis by a practitioner knowledgeable in anatomy, needle insertions are indicated by physical signs and not according to pre-defined, non-scientific meridians, while subjective and objective effects are usually experienced immediately'.[41] The biomedical approaches to acupuncture practice are considered by some to be superior to the archaic and mystical foundations of classical Chinese acupuncture.[42] Others support the view that the traditional Chinese model has no basis in science[43] and that Chinese acupuncture theory is just too hard to learn.[44] Dommerholt, del Moro and Grobli[12] note that some patients erroneously think that MTrP dry needling (TrP-DN) is acupuncture but assert that they are wrong because, in their view, the practice did not originate from traditional Chinese acupuncture, is based on neurophysiologic principles, and has no similarity with regulating the flow of energy. Dommerholt et al[12] assert that, although Gunn used the term acupuncture instead of IMS in earlier papers, his thinking was not based on Chinese acupuncture theory but on neurology and segmental relationships, and therefore that IMS is not acupuncture.

Acupuncture by another name

Denials that TrP-DN and IMS are acupuncture seem difficult to sustain. Gerwin notes that 'Acupuncture trigger point needling is identical to the dry needling technique described by physical therapists, physicians and others'.[45] Trigger point acupuncture is also considered to be part of medical acupuncture,[27] is taught as part of western acupuncture,[24] and is the same as classical *ashi* acupuncture.[31] Gunn's comments regarding the need for

a medical examination and knowledge of anatomy and the individual selection of treatment points describe well the contemporary acupuncture education models in many parts of the world, particularly in China[46] and Australia.[3,47] Acupuncture point descriptions may be standardised in textbooks,[48] but the practitioner is also advised that point descriptions are to take the practitioner to the vicinity of the point and that sensitivity to finger pressure is the most important guide to point location.[48,49] Dommerholt et al's discussion on the origin of MTrPs credits sixteenth century and nineteenth century European physicians' observations[43] but ignores Sun Si Miao's seventh century discovery of *ashi* points.[31]

A distinction offered for TrP-DN and IMS to be considered separate to acupuncture is its foundation in biomedical theory and neurophysiologic explanations of the mechanism of action.[35] Despite research into hypotheses of the mechanisms of action of needling a MTrP, the mechanism remains unknown,[35,50,51] and the aetiology of MTrP remains speculative.[43] The detection of MTrPs is based solely on the clinician's palpatory skills with no objective diagnostic criteria validated.[52] Rather than being based in scientific theory, TrP-DN and IMS are based on empirical models[12,37] with explanatory models developed to explore clinical phenomenon. Even though some acupuncture practitioners may prefer to practise strictly in accordance with classical theory, other acupuncturists incorporate biomedical research into their practice.[15,23] The relationship between the biomedical foundation of TrP-DN and clinical practice describes a variation of classical acupuncture rather than the invention of a new therapy.

Once registration was implemented in Victoria, it became illegal to use the title 'acupuncturist' or to hold out to be qualified to practise acupuncture unless suitably registered or endorsed.[53] The subject 'myofascial acupuncture for myotherapists' taught to remedial massage therapists[54] at one institution became 'myofascial dry needling'[55] once the title 'acupuncturist' was restricted to qualified and registered or endorsed practitioners. Rather than discussions based upon explanatory models, in this context the term 'dry needling' is used pragmatically to overcome the legal sanctions of holding out to practise acupuncture when not registered or endorsed to do so.

Serious risks of dry needling

Descriptions of the serious theoretical risks associated with the practice of dry needling include pneumothorax[37], peripheral and central nervous system injuries, organ puncture and syncope.[34,56] The incidence of these events among practitioners trained in dry needling or IMS is unknown. A literature search using the keywords 'dry needling' and 'risk' was conducted on Medline, Pedro and Scopus without date restriction and limited to English language results (see Table 1). A total of 108 results contained articles relating to acupuncture risks and only one case report of an adverse event from dry needling. No review articles relating to dry needling risks were identified.

The lack of reports of serious risks from dry needling requires some discussion. It may be that despite its deep needling techniques dry needling is safer than acupuncture and has not led to sufficient harm to warrant investigation. It may be that the practice of dry needling is not as widespread as acupuncture and, considering its relatively recent use,[33] has not attracted the attention of investigators. It may also be that as acupuncture and dry needling are considered by researchers, practitioners and patients to be essentially the same practice and that research on acupuncture has been used to inform the risks of dry needling. Support for this latter possibility is provided by papers including a Cochrane review[51] which use the terms acupuncture and dry needling collectively.[50,51] Kalchiman and Vulfsons's discussion of the risks of dry needling provides further support for this notion where they refer to the risks of dry needling as similar to acupuncture and which are 'well described'.[34]

Given the foregoing discussion and that the practice of dry needling is identical to the practice of trigger point acupuncture[45] and *ashi* acupuncture[31] the serious risks associated with acupuncture can be extrapolated to understand the risks of dry needling. A search of English language articles in Scopus using keywords 'acupuncture' and 'risks' and limited from the year 2000 to 2011 resulted in 1 604 results. A further restriction to 'serious risks' limited results to 92; twenty-three of which pertained to acupuncture risks. Results comprised nine review articles, six case reports, four prospective studies, three articles discussing risks and safe practices, and one randomised controlled trial (see Table 2).

Acupuncture is considered safe when practised by well trained practitioners.[57] However, acupuncture has also been associated with a range of serious complications including death.[58] A systematic review of deaths after acupuncture found that 86 fatalities were reported among 32 articles.[58] The most common cause of death was pneumothorax followed by puncture of the heart, large blood vessels, central nervous system structures, the liver or infection.[58] The number of deaths have increased over time and are not limited to China, Japan and other parts of Asia but include deaths in the United States, Germany and Norway.[58] The authors note that pneumothorax is not only the most common cause of death but also the most frequent serious non-fatal complication arising from acupuncture. The authors observe that all deaths would likely be avoided with adequate acupuncture training.[58] In another review the authors speculate on the reasons for different rates of reporting from different Asian and Western countries but conclude that adverse events would be avoided if all acupuncturists were trained to a high

level of competency.[59]

In an Australian study of adverse events in Chinese medicine (primarily acupuncture) it was found that[60] 'adverse event rates for practitioners with 0–12 months of CAM (complementary and alternative medicine) education were significantly higher than for those with 37–60 months education'. In the same study it was found that the risk of pneumothorax among medical practitioners practising acupuncture was twice the rate of non-medically trained acupuncturists.[61] The study found that only 25 of 458 medical practitioners surveyed had completed more than 12 months of traditional Chinese medicine (TCM) education with the remaining 72% either not answering the question on training or had completed less than two weeks of training.[61]

While studies into deaths and serious risks associated with acupuncture support thorough training in acupuncture, there is an assumption that much of this study should be focused on anatomy.[37,62,63] The Australian study demonstrates that it is not enough to have thorough training in anatomy and biomedicine alone. Comprehensive training in acupuncture seems to be associated with a lower risk profile than being a medical practitioner.[61] TrP-DN and IMS favour deep needling methods[29] which carry an inherently greater risk of organ puncture than superficial methods. It should be noted that courses on dry needling in Israel, Canada, the US and Australia are all in the range of 16–36 hours duration[27,34] and fall into the higher risk category found in the above study.[61]

Discussion

Acupuncture is neither a single technique nor underpinned by a single explanatory model.[15,19,64] For thousands of years acupuncture theory has been developed and refined, useless theory has been discarded and innovations incorporated.[19,46,64-66] Acupuncture is evolutionary and different cultures have adapted it to local conditions and modified acupuncture theory and practice over time. Japanese[66,67], Korean[68] and French variants[69] are well established and the concepts of medical acupuncture[23] and western acupuncture[24] have emerged.[51] Research has continued to explore the mechanism of acupuncture from a biomedical perspective for more than five decades and, while some elements of the mechanism have been uncovered,[17] a comprehensive understanding of the mechanism of acupuncture regarding MTrP[43,51] remains elusive.

TABLE 1 Search Strategy and Results for Dry Needling and Acupuncture risks

Database	Medline	Pedro	Scopus	Scopus
Date Range	1977-2011	no restriction	no restriction	2000–2011
Search Terms	Dry needling AND risks	Dry needling AND risks	Dry needling AND risks	Acupuncture AND Risks: 1604 results; limited to serious risks
Search type	Keyword and SmartText via Ebscohost search	Title and abstract	Title, abstract and keyword	Title, abstract and keyword
Results	91	11	6	92
Results for acupuncture risks	2	1	0	23
Results for dry needling risks	1	0	0	0
Total needling risks results	3	1	0	23

TABLE 2 Results of acupuncture risks by article type

Article type	Case Report	Review	Prospective study	Discussion of Risks & Safe Practice	Randomised Controlled Trial	Total
Number	6	9	4	3	1	23

It is inaccurate to label a practice that has become popular over the past decade or so as a new or different practice when it is virtually identical to another practice that has been established and used for more than a thousand years.[31,45] Advocates of dry needling argue that it is the explanatory model underpinning dry needling that differentiates it from acupuncture.[35,37] The explanatory models they refer to are incomplete,[35,45,52] have not been validated,[52] and at best fall into the category of research into the mechanism of acupuncture. It is clinical experience rather than the gold standard of evidence-based medicine that guides dry needling, IMS and medical acupuncture practice.[43,52,70]

Dry needling, IMS and MTrPs have added another chapter to the story of acupuncture by systemising elements of classical practice. This systemisation appears to make it easier to achieve clinical results for neophyte practitioners[34] in the same way that 'cook-book' fixed-point prescriptions of acupuncture[71] have been used previously. These approaches should prove a valuable addition to the curriculum of comprehensive acupuncture programmes along with other modern innovations such as auriculotherapy, laser stimulation, electro-acupuncture and point injection therapy.

The preceding reviews of serious risks link them with negligence and indicate that serious risks can be avoided with adequate training.[72] An Australian insurer[73] noted an increased incidence of pneumothorax among physiotherapists practising acupuncture in 1996 and expects the incidence to increase as more physiotherapists take up acupuncture. The insurer reminds physiotherapists of the need for adequate training and to provide adequate explanations to patients.[73] Negligence is a professional act or omission leading to a patient's harm.[74] By contrast an inherent risk of practice is a risk that cannot be eliminated from a procedure even when a procedure is correctly performed.[74] Under Australian law, failure to warn a patient of an inherent risk may lead to an action of negligence.[74,75] It may be that the short courses and deep needling techniques associated with these two or three day courses popular among physiotherapists[6] make pneumothorax an inherent risk among such practitioners. This shift in thinking is already reflected in some countries with consent forms declaring the risk of a pneumothorax from dry needling to patients before proceeding with treatment.[76-78]

The World Health Organization's (WHO) Guidelines on Basic Training and Safety in Acupuncture (GBT) recommend that allied health practitioners who are not prepared to complete a full 2500 hour program of study in acupuncture should study acupressure instead because of the risks associated with brief training in acupuncture.[79] Redefining the practice of acupuncture to dry needling could be seen as an attempt to avoid the conflict of non-compliance with well established educational and safety guidelines developed by WHO. The range of health practitioners practising acupuncture safely at bachelor's or master's degree level[3] is confounded by the growth of two day courses in dry needling.[3] It may be difficult for the public to discern between a practitioner who is registered or endorsed to practise acupuncture from a practitioner who is practising dry needling when, to the public, elements of each practice appear to be the same.[12]

The relatively small number of deaths from cervical spine manipulation numbering 26 worldwide[80], and associated non-fatal strokes[81], have been sufficient to restrict this practice in Australia to chiropractors, osteopaths, medical practitioners and physiotherapists.[5,81] A risk analysis has shown that the reduced competition that a restriction of practice entails is warranted if it is outweighed by the risk posed to public health and safety through not restricting the practice.[81] The incidence of deaths from poorly trained acupuncture practitioners is more than three times higher than for cervical spine manipulation[58]. The proliferation of short courses under the label dry needling[3] using deep needling techniques will only increase the number of poorly trained practitioners and the incidence of serious risks.[73]

Conclusion

If dry needling were truly a new and different practice to acupuncture then the evidence of its safety should be obtained before this invasive procedure, with potentially serious or fatal inherent risks, is offered to the public. If dry needling is the same practice as acupuncture then the research into the adverse events and serious risks of acupuncture should inform an adequate education and training standard for the practice.

The paper has demonstrated that dry needling is not a new or separate practice from acupuncture which has its roots in Chinese medicine and which continues to evolve and develop within the domains of scientific research, medical acupuncture and Chinese medicine. Dry needling is a pseudonym for very brief training in myofascial acupuncture also known as trigger point acupuncture and *ashi* acupuncture. The deep needling techniques which are preferred and characteristic of the dry needling approach have an inherently higher risk of pneumothorax and other serious risks than other needling methods. Acupuncture is safe in well-trained hands; however the risk of serious adverse events, though rare, has been found to be much higher among practitioners who have minimal training in acupuncture even if they have detailed knowledge of anatomy and biomedicine. The World Health Organization's GBT make it clear that short courses in acupuncture are an unnecessary risk and that acupressure should be studied instead.

In the contested market place of acupuncture practice in Australia, the use of the term 'dry needling' appears to be an attempt to circumvent the role of the well qualified acupuncture workforce and substitute them with other health professions who practise with a rudimentary understanding of just one tool in the acupuncturist's tool-kit. While acupuncture may offer a great contribution to public health, the education standard underpinning the practice of dry needling poses a real threat.

In the Australian context all registered health professions have access to education programs which make them eligible for registration or endorsement in acupuncture. It is not in the public interest to allow poorly trained practitioners to provide an invasive procedure with inherent risks of harm when suitable training courses and well trained professionals are available instead. Short courses in acupuncture to a wide audience under the label 'dry needling' may be profitable; however they appear not to be in the public interest. The practice of acupuncture including its several pseudonyms should be restricted to suitably registered or endorsed acupuncturists in accordance with the NRAS in order to adequately address the risks posed by brief training in acupuncture.

TABLE 3: Glossary of Abbreviations and Acronyms

AHPRA	The Australian Health Practitioners Regulatory Agency
CMBA	Chinese Medicine Board of Australia
CMRBV	Chinese Medicine Registration Board of Victoria
GBT	World Health Organization Guidelines on Basic Training and Safety in Acupuncture
HPRA	Health Practitioners Registration Act 2005
IMS	Intramuscular Stimulation
MPS	Myofascial Pain Syndrome
MTrP	Myofascial Trigger Point
NRAS	National Registration and Accreditation Scheme for the Health Professions
TCM	Traditional Chinese Medicine
TrP-DN	Trigger Point Dry Needling
WHO	World Health Organization

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